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Title Page

A systematic review of psychosocial needs assessment tools for dermatological caregivers

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A systematic review of psychosocial needs assessment tools for dermatological caregivers

ABSTRACT

Objectives: Although skin disease is the fourth leading cause of global disease burden, no comprehensive review of psychosocial needs assessment tools validated for use among dermatological caregivers has been conducted to date. We aimed to identify available and useful psychosocial needs assessment tools to inform evidence-based decisions and promote caregiver health outcomes within daily clinical practice. A secondary objective was to assess the adequacy of measurement properties.

Method: A systematic review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Electronic databases including EMBASE, PsycINFO, MEDLINE (in Ovid SP), Cochrane and CINAHL EBSCO were searched (2000-2020). Title, abstract, full-text screening and data abstraction were done in duplicate.

Results: A total of 8796 records, of which 185 full-text articles were examined. Following quality appraisal, 26 articles were identified. 11 assessment tools were included in this review. An overview of the adequacy of the measurement properties, study and questionnaire-specific information relevant to included tools is provided. Despite the high number of dermatology and disease-specific needs assessment tools identified, limited evidence supports the quality of their methodological and measurement properties. Most tools assessed the patients’ quality of life or were generic quality of life (QoL) tools. Of those tools which are validated for use among caregivers, the majority are either relevant to spouse/partner or depend on the caregiver to complete but are based on their child’s perception of the disease.

Conclusion: With an ever-increasing demand on limited and valuable healthcare resources, there is justification to develop an accessible integrated solution-focused needs assessment tool which will facilitate caregivers to self-report their needs and enable clinicians to identify and triage unmet psychosocial care needs, potentially reconceptualising global burden within the construct of ‘prevention is better than cure’.

Strengths and limitations of this study

- The first systematic review to provide a comprehensive overview of psychosocial assessment tools validated for use among dermatological caregivers of paediatric patients.
- This study was conducted with the involvement of a health and life subject-specific librarian and an international multi-disciplinary expert group.
- The protocol was registered with the PROSPERO database (CRD42019159956) and conducted according to the recommendations from the PRIMA statement and ENTREQ statement.
- Adequacy of measurement properties was assessed using Both *et al*'s criteria
- Included articles were limited to being published in English between 2000-2020.

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INTRODUCTION

Paediatric dermatology is a unique speciality in that children with lifelong and life-limiting skin disorders are increasingly being cared for by caregivers at home¹, which requires considerable cognitive, emotional, and physical resources.² Skin disease is the fourth leading causes of global disease burden with associated prevalence, care requirements and costs comparable with other diseases, such as cardiovascular disease and diabetes.³⁻⁵ Delayed identification of dermatological caregiver needs and provision of timely supports can seriously compromise the long-term psychosocial wellbeing of caregivers ⁶⁻¹⁰ and particularly undermine the care and treatment of paediatric patients affected by rare or chronic skin disease.¹¹ Caregivers of skin disease requires similar systems of monitoring and integrated biopsychosocial support as other comparable chronic conditions.

The World Health Organisation (WHO) directive,¹² recent international guidelines^{13,14} and reports^{9,15-16} emphasise the importance of identifying psychosocial needs assessment tools for use among long-term caregivers, particularly self-referral models. A psychosocial needs assessment could be considered preventative in nature, by anticipating caregiver burnout and decreasing the need for emergency interventions. Despite this, there is a lack of evidence regarding the use of caregiver assessment tools within healthcare settings. Timely and appropriate identification of caregivers’ unmet psychosocial needs has the potential to reduce caregiver strain, increasing their ability to provide care within the home, reducing health costs and improving the quality of life for both caregiver and care recipient. With increasing competition for valuable healthcare resources and services, there is an urgent need to inform service delivery by providing caregivers with an opportunity to self-articulate their needs and supports.

This review aimed to improve clinician access to existing psychosocial needs assessment tools, validated for use among dermatological caregivers to inform evidence-based decisions and promote caregiver health outcomes within day-to-day clinical practice.

METHODS

A protocol for this systematic review (CRD42019159956) was published online on PROSPERO. This review was registered on the COMET database and conducted according to the recommendations from the PRIMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement.¹⁷ The ENTREQ statement was read and guided in reporting the synthesis of the findings.¹⁸

Ethics Approval Statement

Ethical approval for this review was obtained from University of Ulster Research Ethics Committee (Ref: REC/20/0004). Informed consent was obtained from all participating members of the expert group associated with the research project.

Literature search and screening

We searched in MEDLINE, PsycINFO and EMBASE using the OVID interface (2000 to April 2020). CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature) was additionally searched (2000 to April 2020). Grey literature, bibliographies, online databases of QoL tools and several trial registers were also searched (2000 to April 2020). Appendix 1 shows the robust search strategy used to search EMBASE. This strategy was tailored to the specifications of each of the databases searched and developed in collaboration with a subject-specific librarian (J.A.) and expert group. Pre-planned keyword searches were limited to titles and abstracts, with MeSH terms being exploded, where available. Each keyword was individually mapped to appropriate subject headings (MeSH) in each database, where available, to ensure a broad and thorough search. Each concept was taken individually and OR MeSH with the keyword(s). This process was repeated with all five concepts and were AND together at the end. Date and language limits were then applied. After the search was run, inclusion/exclusion criteria were then applied. Title, abstract and full-text screening were conducted independently in duplicate by two reviewers (C.W. and G.L.) according to the eligibility criteria. At the full text screening stage, any discrepancies, including on the risk of bias, were resolved by discussion until a consensus was reached.

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Eligibility criteria

Studies which involved adult caregivers (age 18 years and over) caring for a child (no age limit) with any form of any skin condition were reviewed. Included articles were limited to being published in English between 2000-2020. This ensured that relevant assessment tools developed in the years before publication of the 2017 review¹⁹ were included as that review had limited their search to one database and quality-of-life measures only, which contrasts with the measures recommended by the Cochrane Skin Centre of Evidence Based Dermatology as outlined later in this review. We did not include a specific definition of psychosocial because, given a lack of consensus in the literature on the use of this term, we wanted to include a diverse range of tools (cognitive, social and emotional) to answer the research question. Reasons for excluding full text articles are outlined in Fig. 1.

Data extraction

Extracted data on full-text articles was completed in duplicate by two reviewers independently (C.W. and G.L.) on two standardised extraction forms. After data collection, an overview of methodological analysis of the included instruments was conducted using Both *et al*'s²⁰ criteria, made possible by the similarities between the studies.

Patient and public involvement

An international multi-disciplinary expert group (n=15), including affected adults, clinical psychologists, consultant dermatologists, health policy advisors and caregivers, was established at the outset of the project (September 2017). Individual emails of invitations and information sheets were sent in advance of online multi-method consultations (email, telephone, focus groups). Ethical approval for the project and informed consent was obtained from all participating members. Anonymity remains protected due to their ongoing involvement in another follow-on study. The Guidance for Reporting Involvement of Patients and the Public (GRIPP) Short Form checklist was used to improve the reporting of PPI in our study.²¹ The aim of PPI in this study was to help identify the research question, guide in terms of review design (search strategy, inclusion and exclusion criteria and data extraction subheadings) and improve the dissemination of findings (invitations to poster and orally present at international dermatology and psychology conferences, pharmaceutical industries and health statutory committees, academic publications). They were not invited

to contribute to the interpretation, writing or editing of this document for readability and accuracy. The caregiver relevant research question was developed in response to their priorities, experiences and preferences. It aimed to improve clinician knowledge and access to relevant tools to inform evidence-based decisions and promote caregiver health outcomes within day-to-day clinical practice.

RESULTS

The database searches resulted in 8085 records and 711 records were identified through other sources as outlined in the PRISMA flow chart (Fig. 1). A total of 185 articles were read in full text from which 159 articles were excluded for reasons outlined in Fig. 1. No records were identified from searching grey literature or the trial registers listed in Table 1. The majority of existing, validated dermatological assessment tools are generic quality of life (QoL) tools and/or assess the patients' quality of life. Of those tools which are validated for use among caregivers, most are either relevant to spouse/partner or depend on the caregiver to complete but are based on their child's perception of the disease. Very few needs assessment tools are validated for use among dermatological caregivers despite many caring for children affected with rare and/or chronic skin disease.

From the 26 articles included in this review, a total of 11 assessment tools were identified.²²⁻

³² Ten disease-specific assessment tools were identified (**PFI-15²²**, **Family Pso²³**, **QPCAD²⁴**, **CADIS²⁵**, **PIQoL-AD²⁶**, **DFI²⁷**, **PASECI²⁸**, **CarGOQoL²⁹**, **EB-BoD³⁰** and **FBI³¹**) and one dermatology-specific assessment tool was identified (**FDLQ³²**). Table 2 provides a summary of study-specific information and includes the name of tool, country of origin, disease of affected patient, sample sizes and study setting. Table 3 summarises questionnaire-specific information under the subheadings domains, subscales, number of items, recall period, scoring system and administration time. Table 4 provides an overview of the adequacy of the measurement properties of the included tools, including transferability, reliability, validity, structural and interpretability.

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Disease-specific needs assessment tools

The Family Psoriasis Index (PFI-15)²² is recommended for use alongside a dermatology-specific tool. As it is assessed on current time only it does not rely on accurate recall. However, due to the small sample size, factor analysis could not be done and there is a lack of comparison of PFI scores with other generic family QoL scales. In order to achieve its Cronbach alpha value (0.86), it was necessary to delete five items. It has a weaker focus on the emotional aspects of living with affected members. Those accompanying patients to the primary care centre and inpatients were not included in the creation of the PFI, which restricts the generalisation of the quantitative findings.

The Family Pso²³ was created from interviews (n=95) with psoriasis patients and their family members. Three experts (no caregiver involvement) decided the generation items for piloting and item reduction. Other limitations include that a small sample was used in its testing and were predominantly female partners of the interviewees. Its advantages include that the wording is more focused on emotional aspects of caregiving as opposed to HR-QoL.

Four tools were found that assess the impact of atopic dermatitis on the family. The **Quality of life in Primary Caregivers of Children with Atopic Dermatitis (QPCAD)**²⁴ has a one week recall and has been validated for use among primary caregivers of children with AD in the Japanese version only. Convergent validity requires further study and only caregivers of mild and moderate patients from an urban area were included in the study.

The **Childhood Atopic Dermatitis Impact Scale (CADIS)**²⁵ is validated for use with both patients and parents of patients younger than six years. Rasch analysis reduced the tool to a 45-item version which is responsive to clinical change in AD.

The **Parents' Index of Quality of Life in Atopic Dermatitis (PIQoL-AD)**²⁶ assesses the impact of AD on caregivers of affected children, aged eight years or younger. The PIQoL-AD adopts a dichotomous response system which is less sensitive to subtle changes in HR-QoL and includes only items that considers the negative aspects of psychological well-being.

The **Dermatitis Family Impact (DFI)**²⁷ tool is the tool most widely reported in studies, having been used in over 750 clinical trials, although often at longer intervals despite being validated for use with a one-week recall period. As the majority of DFI studies are in

secondary care hospitals, there exists the possibility of maximising the chances of the DFI scores showing significant improvements following an intervention.²⁷ Dodington's review³³ found that internal consistency and test-retest reliability was adequately demonstrated, but highlighted that psychometric measures were less well established due to a lack of vigour in both the creation and validation processes. No valid score-banding descriptors of DFI score meanings are included and no information to establish the MCID of DFI score is available.²⁷ No studies demonstrated dimensionality, factor structure or differential item functioning.

The final tool included in this review was the **Parental Self-Efficacy with Eczema Care Index (PASECI)**²⁸. It is a generalised self-efficacy scale focusing on the management of four subscales; medication, symptoms, personal challenges and communication with healthcare teams. It has a two-factor structure which considers the performance of routine management tasks and the management of child symptoms and behaviour. There was reliance on self-reported data, potentially affecting the fidelity of the results. More research is needed on banding and categorisation.

Validation of **The CareGiver Oncology Quality of Life (CarGOQoL)**²⁹ was carried out using dermatology experts other than caregivers. Several non-optimal indicators of validity are indicated in Table 4.

The **Epidermolysis Bullosa – Burden of Disease (EB-BoD)**³⁰ tool needed to remove non-discriminatory items, such as frustration and guilt, from the original FBI³¹ during its creation. It requires further validation in larger EB patient and/or caregiver groups before being revalidated for use in other languages and cultures.

The Family Burden of Ichthyosis (FBI)³¹ is the only validated disease-specific questionnaire which measures the concept of burden for ichthyosis caregivers. The monocentric study used parents and their affected children in the creation of verbatim using an unnamed French social assessment, which could not be accessed for this review. Selection bias was a possibility as 40% of participants cared for those affected by severe forms of ichthyosis (severity score 50 or greater). Limitations include that validation of the FBI was carried out using parents of children affected with only the severest forms of ichthyosis. Although itch is one of the significant challenges named by parents of children affected with ichthyosis (third most significant impact during the validation of the DFI²⁷), it does not feature as an item.

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Similarly, no items relate to pain in the finalised FBI.³¹ Verification of its psychometric properties, preferably in a multicentre study is required. Caregiver feedback included that the finalised generation items were negatively phrased. The original French questionnaire has been linguistically and culturally adopted in Italy.³⁴

Dermatology-specific needs assessment tools

The **Family Dermatology Life Quality Index (FDLQI)**³² is the most commonly used dermatology-specific HR-QoL. The psychosocial impact loaded six items (emotional impact, physical wellbeing, impact on relationships, leisure, social life, and people’s reactions) and the physical impact loaded four items (burden, effect on job/study, household expenditure and housework). Fifty semi-structured interviews took place with informed the items generated for testing during piloting. The feedback (n=59 items) from these interviews has been termed ‘the greater concept’. Piloting of the 19 items occurred with 20 parents or partners of those originally interviewed, potentially introducing bias. Limitations include that the life-course of skin disease is not reflected in the FDLQI and that it depends on recall accuracy. Definitions, such as MID and the meaning of FDLQI scores are missing and future research is required to show the unidimensionality of the tool. The FDLQI was not tested for responsiveness for clinical change in a hospital or intervention context. There are several items of the FDLQI which cannot discriminate between inflammatory and uninflammatory groups.

The main theme which emerged was the variation in methodological rigor used in measuring caregiver needs. The findings from this systematic review indicate an incomplete psychometric overview and the generalisability and interpretation of results remain limited. The lack of psychometric evidence on many of the included questionnaires is alarming. All included assessment tools (11 of 11; 100%) evaluated four or more psychometric properties. They do not comply with the OMERACT filter criteria and consequently are unable to be included in the development of a future COS.⁴⁸ In terms of structure, five tools reported the use of factor analysis.^{23,28-30,32} Three tools reported the use of the more recently developed item response theory (IRT) to determine psychometric properties.^{22,25,26} Other tools neither reported factor analysis or IRT.^{24,27,31} Apart from two

tools reporting strong item bias^{22,26}, the other nine tools^{23-25,27,28-31,32} reported weak item bias. One tool²⁷ reported the use of distribution-based categorisation techniques, but the other ten tools did not report on categorisation. MCID was not reported for any tool other than one²⁶. In terms of reliability, all tools reported a high internal consistency (IC>0.95). Two tools did not report their retest reliability.^{23,31} One reported a weak retest reliability²⁹ (ICC<0.70), while the other eight tools reported a good retest reliability^{22,24-28,30,33} (ICC>0.70). In terms of conceptual validity, four tools have less well-balanced domains.^{24-26,29} The other seven tools include well balanced domains.^{22,23,27,28,30-32} No information is given regarding the construct validity for one tool.²³ Five tools demonstrate that <75% of results are in accordance with their hypothesis^{27,28-31} and five tools demonstrate that >75% of results are in accordance with their hypothesis^{22,24-26,31}. The majority of tools demonstrate poor convergent validity apart from two^{27,28} (>0.70). The PFI-15 provides no information on convergent validity.³² The other eight tools in this review show a convergent validity value of <0.70.^{23-26,29-32}

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Table 1: Results from additional tools included in search strategy

Tools included in search	Search category/term	Results	Number accessed in full text	Relevant (included in review) in
Controlled Trials ISRCTN (www.controlled-trials.com/isrctn/)	'Skin and Connective Tissue Diseases'	241	3	0
United Kingdom (UK) Clinical Trials Gateway (www.ukctg.nihr.ac.uk/default.aspx)	'Skin and Cosmetic health'	72	0	0
United States(US) National Institutes of Health Ongoing Trials Register (www.clinicaltrials.gov)	'caregiver' and 'skin diseases'	24	1	0 (recruitment stage)
Australian New Zealand Clinical Trials Registry (www.anzctr.org.au)	'caregiver' and 'skin'	25	0	0
World Health Organization International Clinical Trials Registry platform (www.who.int/trialsearch)	'skin' and 'caregiver'	182	0	0
EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/)	'skin' and 'caregiver'	30	0	0
British Library Electronic Theses Online Service (EThOS) was searched using several combinations of key words	skin, instrument, caregiver, validation, psychosocial	2	2	0
OpenGrey database (www.opengrey.eu/) was searched (up to 22 November 2013)	'Skin Diseases'	87	0	0
Patient-Reported Outcome and Quality of Life Instruments Database (PROQOLID) (2002)		0	0	0
Cochrane Central Register of Controlled Trials (CENTRAL)	'skin' and 'caregiver' and 'skin disease' and 'dermatological tool'	56	0	0
Handsearching of the bibliographies of included and excluded studies		48	0	0

Table 2: Study-specific Information relevant to included assessment tools

References of included publications (first author, year, reference)	Country of Origin	Disease of affected patients	Name of Measurement Instrument	Sample size (n)	Study setting
Eghlileb et al ²² (2009)	United Kingdom (UK)	Psoriasis	Psoriasis Family Index (PFI-15)	Interviews (Unknown)	Monocentric Outpatient clinic
Mrowietz et al ²³ (2017)	Germany	Psoriasis	Family Pso QoL in Primary Caregivers of children with Atopic Dermatitis (QPCAD)	Interviews (14) Piloting (96) Validation (96)	Monocentric Outpatient clinic
Kondo-Endo et al ²⁴ (2009)	Japan	Atopic Dermatitis	Childhood Atopic Dermatitis Impact Scale (CADIS)	Interviews (unknown) Pilot (33) Validation (400)	Monocentric Outpatient clinic
Chamlin et al ²⁵ (2005)	United States of America (USA)	Atopic Dermatitis	Parent's Index QoL - Atopic Dermatitis (PIQoL-AD)	Interviews (unknown) Piloting (20) Validation (300)	Two dermatology paediatric practices (San Francisco & Chicago)
McKenna et al ²⁶ (2005)	UK, Netherlands, Italy, Spain, USA, Switzerland, Germany, France (simultaneous development)	Atopic Dermatitis	Dermatitis Family Impact (DFI)	Interviews (65) Piloting (140 total) Validation (ranged between countries 45-328)	Monocentric Outpatient clinic
Lawson et al ²⁷ (1998)	UK	Dermatitis		Interviews (29) & Focus Groups (10) Piloting (14) Validation (56)	Monocentric Outpatient clinic

Continued

References of included publications (first author, year, reference)	Country of Origin	Disease of affected patients	Name of Measurement Instrument	Sample size (n)	Study setting
Ersser et al ²⁸ (2015)	UK	Eczema	Parental Self-Efficacy with Eczema Care Index (PASECI)	Literature review-generation items Piloting & Validation (242)	Monocentric Outpatient clinic
Minaya et al ²⁹ (2012)	France	Skin cancer	CareGiver Oncology Quality of Life (CarGOQoL)	Interviews (77) Piloting (837) Validation (unknown)	Monocentric Outpatient clinic
Dufresne et al ³⁰ (2015)	France	Epidermolysis Bullosa	Epidermolysis Bullosa - Burden of Disease (EB-BOD)	Complaints (23) informed item generation Piloting (Lionbridge institution) Validation (55)	Monocentric Outpatient clinic
Dufresne et al ³¹ (2013)	France	Ichthyosis	Family Burden Ichthyosis (FBI)	Interviews (94) Piloting (42) Validation (30)	Monocentric Outpatient clinic
Basra et al ³² (2008)	UK	All - general dermatology instrument	Family Dermatology Life Quality Index (FDLQI)	Interviews (50) Piloting (20) Validation (14)	Monocentric Outpatient clinic

Table 3: Questionnaire-specific information relevant to included assessment tools

Name of Measurement Instrument	Domains measured	Number of items and subscales	Recall Period	Scoring system	Respondent Feedback	Admin Mode (Time in minutes)
Psoriasis Family Index (PFI-15) ²²	Social Life, Leisure activities Sporting activities, People's reactions, Worry about future Housework, Relationships Treatment duration, Clothing Shopping, Sleep	15 items	Now	4-point scale (0-3)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (2)
Family Pso ²³	Emotional Domain-emotional impact. Social Domain -Impact on daily activities & work /school and treatment. Leisure Domain - Influence on leisure/ personal relationships	15 items	1 month	5-point Likert format (0-4) and 'Does not apply'	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (3)
QoL in Primary Caregivers of children with Atopic Dermatitis (QPCAD) ²⁴	Achievement (3) Worry (6) Family co-operation (3) Exhaustion (8)	19 items	Past week	5-point scale (none to extremely)	Brief in length Moderate to administer, score and interpret Conflicting evidence of alternative forms	Self-report (unknown)
Childhood Atopic Dermatitis Impact Scale (CADIS) ²⁵	Impact on family (3 domains) Sleep and emotions Family & social function	45 items	1 month	5-point scale (never to all the time)	Long in length and problems of acceptability Moderate to administer, score and interpret Absent evidence of alternative forms	Self-administered (6)

Continued

Name of Measurement Instrument	Domains measured	Number of items and subscales	Recall Period	Scoring system	Respondent Feedback	Admin Mode (Time in minutes)
Parent's Index QoL - Atopic Dermatitis (PIQoL-AD) ²⁶	1 domain - needs that can be influenced by a child with a diagnosis of AD	28 items	Not reported	5-point scale (never to all the time)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (3)
Dermatitis Family Impact (DFI) ²⁷	Personal relationships and helping with treatment, Food and feeding, Sleep, Housework Shopping, Financial, Leisure Tiredness, Emotional distress	10 items	1 week	4-point scale (not at all, a little, a lot, very much)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (unknown)
Parental Self-Efficacy with Eczema Care Index (PASECI) ²⁸	Managing medications Managing eczema & symptoms Communication with Healthcare teams Managing Personal challenges	29 items 4 subscales	1-week pre and 4 weeks post intervention	11-point Likert Scale	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Clinician administered (3)
CareGiver Oncology Quality of Life questionnaire (CarGOQoL) ²⁹	Psychological well-being, Burden, Relationship with health care, Administration and finances, Coping, Physical well-being, Self-esteem, Leisure time Social support and private life	29 items	1 week	5-point Likert scale (never/not at all, rarely/a little, sometimes/somewhat, often/a lot, always/very much)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (3)
Epidermolysis Bullosa - Burden of Disease (EB-BOD) ³⁰	Economic and Social impact (5) Family Life (7) Disease & Treatment (5) Child's Life (3)	20 items	Not stated	7- point scale (always, very often, often, sometimes, rarely, never, not applicable)	Moderate to administer, score and interpret Absent evidence of alternative forms Long in length and problems of acceptability	Self-administered (unknown)

Continued

Name of Measurement Instrument	Domains measured	Number of items and subscales	Recall Period	Scoring system	Respondent Feedback	Admin (Time in minutes)	Mode in
Family Burden Ichthyosis (FBI) ³¹	Work & Psychological impact, Daily Life, Pain, Familial and Personal Relationships	25 items	Not stated	4-point scale (definitely yes, maybe, definitely not, I don't know)	Long in length and problems of acceptability Moderate to administer, score and interpret	Self-administered (3)	
Family Dermatology Life Quality Index (FDLQI) ³²	Housework & expenditure Emotional & Physical wellbeing Impact on study/job, Social Life Burden of care, Leisure Activities	10 items	1 month	4-point scale (not at all/not applicable, a little, quite a lot, very much)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (3)	

Table 4: Adequacy of the measurement properties relevant to included assessment tools with excellent and good methodological quality

Name of Measurement Instrument	Transferability	Reliability	Validity	Structure	Interpretability
Psoriasis Family Index (PFI-15) ²²	Sometimes translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - well balanced domains Construct >75% results in accordance with hypothesis Convergent - No information	IRT Weak sensitivity to detect changes Strong item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
Family Pso ²³	Never translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC not reported or correlation coefficient <0.70	Conceptual - more focused on objective/subjective domains Construct - no information Convergent <0.70	Factor analysis Weak sensitivity to detect changes Weak item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
QoL in Primary Caregivers of children with Atopic Dermatitis (QPCAD) ²⁴	Never translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - more focused on objective/subjective domains Construct <75% results in accordance with hypothesis Convergent <0.70	Satisfactory response to change in disease severity Satisfactory test retest reliability	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
Childhood Atopic Dermatitis Impact Scale (CADIS) ²⁵	Sometimes translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - well balanced domains Construct >75% results in accordance with hypothesis Convergent <0.70	IRT Strong sensitivity to detect changes Weak item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
Parent's Index QoL - Atopic Dermatitis (PIQoL-AD) ²⁶	Always translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - more focused on objective/subjective domains Construct >75% results in accordance with hypothesis Convergent <0.70	IRT Strong sensitivity to detect changes item bias Strong item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - known in heterogeneous sample

					Norms - General nor dermatology patients
					Categorisation - used distribution-based techniques
					MCID - not reported
Dermatitis Family Impact (DFI) ²⁷	Always translated using guidelines Sometimes analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - well balanced Construct <75% results in accordance with hypothesis Convergent >0.70	No factor analysis or IRT Strong sensitivity to detect changes Weak item bias	
Parental Self-Efficacy with Eczema Care Index (PASECI) ²⁸	Always translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - well balanced Construct <75% results in accordance with hypothesis Convergent >0.70	Factor analysis Satisfactory response to change in disease severity Weak item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
CareGiver Oncology Quality of Life Questionnaire (CarGOQoL) ²⁹	Sometimes translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC <0.70	Conceptual - more focused on objective/subjective domains Construct <75% results in accordance with hypothesis Convergent <0.70	Factor analysis Low / moderate sensitivity to changes Weak item bias	Norms - General nor dermatology patients Categorisation - used distribution-based techniques MCID - not reported
Epidermolysis Bullosa - Burden of Disease (EB-BOD) ³⁰	Sometimes translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - well balanced Construct <75% results in accordance with hypothesis Convergent <0.70	Factor analysis Weak sensitivity to detect changes Weak item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
		IC: 0.95 > Cronbach's α >0.70			
Family Burden Ichthyosis (FBI) ³¹	Sometimes translated using guidelines Never analysed in a cultural equivalence study	Retest reliability: k or ICC not reported or correlation coefficient <0.70	Conceptual - well balanced Construct <75% results in accordance with hypothesis Convergent <0.70	No factor analysis or IRT Weak sensitivity to detect changes Weak item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
Family Dermatology Life Quality Index (FDLQI) ³²	Always translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - well balanced domains Construct >75% results in accordance with hypothesis Convergent <0.70	Factor analysis Strong sensitivity to detect changes Weak item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported

IRT, item response theory; IC, internal consistency; ICC, intraclass correlation coefficient; MCID, minimal clinically important difference.

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DISCUSSION

This systematic review is the first to address gaps in the existing evidence base around the identification of appropriate dermatological caregiver assessment. This review topic represents an emerging area for which there is a lack of up-to-date good quality synthesised evidence. With increasing numbers of patients of chronic skin disease being cared for at home by informal caregivers, often with limited medical training, key international multi-disciplinary stakeholders (including clinicians, dermatological caregivers, and policymakers) emphasised an urgent need to improve clinician awareness of existing needs assessment tools, to help them make informed evidence-based decisions relating to caregiver assessment. The need to promote caregiver health outcomes within day-to-day clinical practice has become even more significant during Covid-19, a period of enhanced social isolation and increased caregiver hypervigilance and burnout.

A total of eleven psychosocial needs assessment tools validated for use among dermatological caregivers were identified and categorised as either disease-specific or dermatology-specific. Although skin disease is often characterised by unpredictable episodes in symptom severity^{29,30,32} and requiring similar systems of monitoring and integrated biopsychosocial support as other chronic conditions,^{5,35} our review highlights the lack of literature pertaining to the use of these assessment tools in healthcare settings. The only dermatology-specific tool validated for use with dermatological caregivers was the ‘Family Dermatology Life Quality Index’ and remains the most used dermatology assessment tool. This mismatch between the recognised impact of caregiving for skin disease and the failure of practitioners to effectively engage with its management may be attributed to the biomedical model of assessment reflected in existing tools.

In contrast to the tools reviewed,²²⁻³² which utilized measures of other constructs as a proxy for caregivers’ need, it is crucial to directly assess caregivers’ needs and employ a plan for how that knowledge will be used to help support these needs³⁶⁻³⁸. None of the tools included in this review used the scope of the International Classification of Functioning, disability and health (ICF)³⁹ to inform their caregiver framework in terms of contextual factors, such as personal capacity and performance and the physical, social and attitudinal world, or in terms of functioning and disability such as participation, body functions and activities. Despite the recognised difficulty of assessing chronic pathologies by clinical or

quality of life (QoL) aspects alone^{40,41}, most tools identified in this review were generic QoL tools. The European Academy of Dermatology and Venereology (EADV) Quality of life task force,⁴² Cochrane Skin Centre of Evidence Based Dermatology⁴³ and the Harmonising Outcome Measures for Eczema (HOME) initiative⁴⁴ reinforce that generic QoL assessments do not encompass the many factors that contribute to the psychosocial burden of skin disease⁴⁵ and are not as sensitive, responsive or relevant to individual patients or their caregivers⁴⁶.

We considered appropriate measurement tools to be theoretically driven, rigorously conceptualized with input from key stakeholders at each stage, consider the life-course of the disease, tested for validity and reliability and intended to assess caregiver needs in relevant settings.^{36,42-44} Potentially, conceptual and theoretical work on dermatological caregivers' needs could be relatively lacking because of the varying degree by which the tools were informed by caregiver experience, with minimal description of the questionnaire development process, absence of or exclusionary key definitions such as family, caregiver and domain and participants were not asked to clarify their relationship to the patient attending the outpatient clinics. Some of the tools only included items for the negative aspect of psychological wellbeing^{27,31,32}.

To be able to comprehensively and effectively provide culturally sensitive care, healthcare teams should have access to validated assessment tools which considers all dimensions along the care continuum and which do not use measures of other constructs as a proxy for caregivers' needs.⁴⁷ An international multicentric approach could best address variables including culture, demographics and disease severity. Although none of the reviewed assessment tools allow for the assessment of disease variables, such as disease severity, it is recommended that future needs assessment tools include disease parameters when designing their assessment framework. Dufresne³⁰ found that increased disease severity led to increased caregiver burden, suggesting that tools which assess factors relevant to clinical severity of disease could better inform the types of supports needed long-term. The lack of validated and well-designed tools creates barriers to accessing healthcare resources, can only serve to weaken a caregiver's sense of autonomy, coping ability and resilience. This is significant considering research highlights that timely and appropriate assessment, whereby caregivers are facilitated to regularly self-report perceived needs and clinicians may identify

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and/or triage unmet support care needs, can lead to better outcomes for both the care recipient and the caregiver. Well-designed needs assessments should help caregivers to identify their needs and strengths as opportunities as opposed to dangers, reinforcing a sense of mastery which has a psychological power than can influence outcomes for both the caregiver and care recipient.³⁶⁻³⁹

Strengths and Limitations:

Strengths of this systematic review include the involvement of a multi-disciplinary expert group and health science librarian in the design of the review, a published protocol, a thorough and comprehensive literature search, provision of study and questionnaire specific information, assessment of measurement properties relevant to each included tool using established criteria²⁰ and the provision of recommendations for key directions for future research. Although challenges existed around the time needed to ensure that members were involved as equal partners in debates and decisions around key issues, benefits of PPI included having experts with lived experience who creatively contributed towards the methodology for this review. In terms of limitations, we only included studies published in the English language between 2000-2020.

In terms of key directions for future research into how dermatological caregiver needs can be met, we recommend assessments adopt a more thorough typology in order to assess the degree to which deficits in caregivers’ needs are present and to develop transparent conceptual frameworks which include key definitions and which are built upon a hybrid model, using existing good quality caregiver frameworks alongside qualitative feedback from large and culturally diverse international cohorts of caregivers.⁴⁹ With increased emphasis on self-referral and e-mental health in healthcare, it seems both desirable and practical to conceptualise an accessible, useful, purposeful and integrated solution-based model of assessment to allow for timely identification and/or triage of unmet psychosocial needs by practitioners. Development of a dermatological caregiver e-tool could potentially address recognised healthcare challenges, including limited clinic appointment times, poor caregiver identification and healthcare communication⁴⁹⁻⁵⁴ and strengthen a caregiver’s sense of autonomy, coping ability and resilience.⁵⁵

CONCLUSION

Although there is no gold-standard tool for measuring the psychosocial needs of dermatological caregivers, this review improves clinician awareness and knowledge of the availability, usefulness and appropriateness of validated dermatological caregiver needs assessment tools. This review provides a comprehensive and thorough review of each of the eleven tools, addressing all identified theoretical and conceptual gaps and assessing methodological quality. It can serve to inform both the development of practices in dermatology care coordination and future assessment tools. As dermatological caregiving research moves forward with significant public and private investment, rigorous measurement of caregivers' needs is essential for the development of social services, public policies and support systems designed to meet the needs of caregivers. These findings have implications for clinical practice, service development and future research and reinforces that attitude towards caregivers is pivotal in developing useful assessment for the purpose of accessing supports and services.

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Data Sharing statement All data relevant to the study are included in the article or uploaded as supplementary information

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Figure 1 Legend:

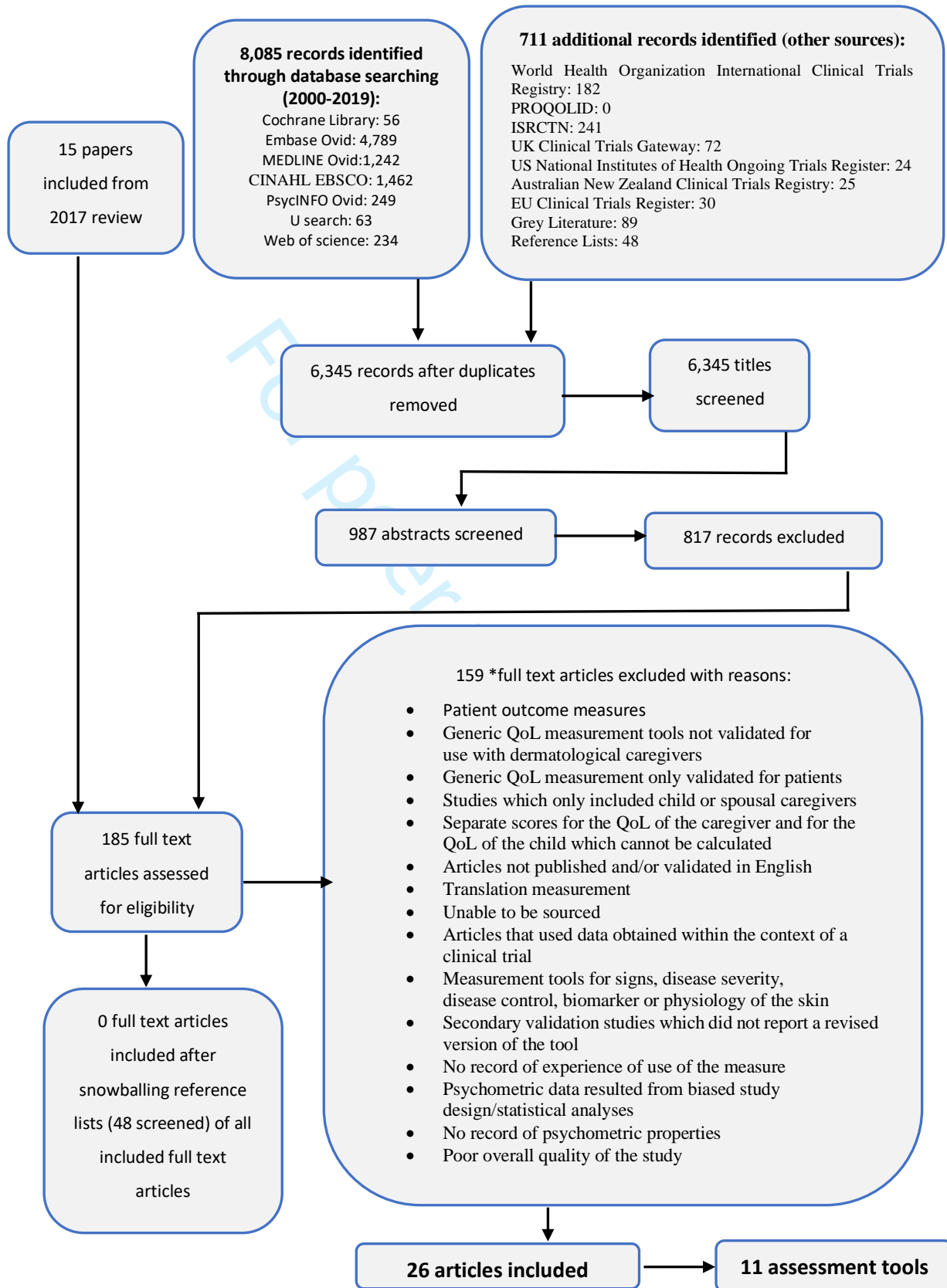
PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.; CINAHL, Cumulated Index to Nursing and Allied Health Literature; EBSCO, Elton B. Stephens Company; PsycINFO, Psychological Information Database; U Search, Ulster University Search; PROQOLID, Patient-Reported Outcome and Quality of Life Instruments Database; ISRCTN, International Standard Randomised Controlled Trials Number; UK, United Kingdom; US, United States; EU, European Union; QoL, Quality of Life.

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Figure 1: PRISMA Flow Diagram



PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.; CINAHL, Cumulated Index to Nursing and Allied Health Literature; EBSCO, Elton B. Stephens Company; PsycINFO, Psychological Information Database; U Search, Ulster University Search; PROQOLID, Patient-Reported Outcome and Quality of Life Instruments Database; ISRCTN, International Standard Randomised Controlled Trials Number; UK, United Kingdom; US, United States; EU, European Union; QoL, Quality of Life.

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1. (Psychosocial or psycho-social or psychodermat* or social or cognit* or emotion* or well-being or psychologic* or adjust* disorder or depress* or anxiety or anxious or coping or stress or mental health or guilt or embarrassment).m_titl.
2. mental disease/
3. behavior/ or cognitive therapy/ or behavior disorder/
4. social participation/ or social support/ or social alienation/ or "social determinants of health"/ or social support assessment/ or social isolation/ or social psychiatry/ or social aspect/ or social network/ or social psychology/ or social isolation stress test/ or social behavior/ or Social Interaction Anxiety Scale/ or social norm/ or social life/ or social interaction/ or Social Support Index/ or social stigma/ or "social aspects and related phenomena"/ or social phobia/ or social acceptance/
5. cognitive behavioral stress management/ or Social Cognitive Theory/ or cognitive therapy/
6. psychosocial care/ or Psychosocial Adjustment to Illness Scale/ or psychosocial disorder/
7. anxiety/ or anxiety assessment/
8. emotion assessment/ or emotion/
9. wellbeing/ or psychological wellbeing assessment/
10. coping behavior/
11. guilt/
12. emotion/
13. depression/ or depression assessment/
14. psychological adjustment/ or adjustment disorder/ or adjustment/ or Psychosocial Adjustment to Illness Scale/
15. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
16. (disease specific or dermatolog* specific or disease burden or burden of disease or scale or needs assessment or psychosocial assessment or index or tool or interview or quality of life or validat* or QoL or measure or impact or screen* or wellbeing or well being or questionnaire or health related quality of life or health profile or assessment* or inventory or intervention or evaluation or schedule or survey or audit or neuropsychological assessment or activities of daily living or dermatolog* specific health instrument or psychosocial impact or psycho social impact).m_titl.
17. disease burden/
18. exp questionnaire/ or exp "quality of life"/
19. clinical assessment tool/
20. psychological interview/ or interview/
21. exp "quality of life"/
22. health impact assessment/
23. exp needs assessment/
24. health survey/ or health care survey/
25. daily life activity/
26. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
27. clinical assessment tool/
28. 26 or 27
29. (Caregiver* or family or 'family caregiver' or 'family care giver'* or parent or homecare* or home care* or adult or adults* or grownup* or

grown up or families or relative or relation* or mother* or father* or family nurs* or primary care provider* or informal caregiver* or carer or
'greater patient concept' or homecare).m_titl

30. caregiver burden/ or exp caregiver/ or caregiver support/ or Caregiver Strain Index/

31. parent/

32. adult/

33. home care/

34. family functioning/ or family coping/ or family life/ or family centered care/ or family stress/ or family health/ or exp family assessment/or
exp family/

35. relative/

36. sibling/

37. grandparent/

38. 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37

39. (Ichthys* or Skin* or skin condition* or skin disorder* or scaliness or keratos* or cornificat* or rare skin dermatology* or chronicdisease
or chronic condition or long term condition or chronic illness or incurable or disability or life limiting or long term care or life threatning or
palliative or assistive technology or continu* of care or chronic car* or continuing car* or impact of chronic skin disese).m_titl.

40. "ichthyosis bullosa of Siemens"/ or X linked ichthyosis/ or ichthyosis/ or lamellar ichthyosis/ or ichthyosis vulgaris/

41. exp skin/ or exp skin disease/

42. psychological rating scale/ or Psychosocial Adjustment to Illness Scale/

43. chronic disease/

44. rare disease/

45. diseases/co, dm [Complication, Disease Management]

46. palliative nursing/

47. eczema/

48. "Psoriasis Area and Severity Index"/ or psoriasis vulgaris/ or Psoriasis Severity Index/ or scalp psoriasis/ or exp psoriasis/

49. atopic dermatitis/ or exp dermatitis/

50. 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49

51. (Child or children or infant* or toddler* or baby or babies or youngster* or young pers* or preschool* or teenage* or adolescen*
orprematu*).m_titl.

52. exp child/

53. infant/

54. preschool child/

55. toddler/

56. adolescent/

57. baby/

58. 51 or 52 or 53 or 54 or 55 or 56 or 57

59. 15 and 28 and 38 and 50 and 58

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2,5,6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	5
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	11, Fig 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6, Fig 2
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	29
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5,17,18

Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Data extraction forms (Tables 2-4, p12-18)
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	7, 17, 18



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	5
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	6, Table 4 (p17)
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	7
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	7, Tables 2-4 (p12-18)
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	5, Table 4 (p 17)
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	8-10, tables 2-4 (p12-18)
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	8-10
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	5, Table 4 (p 17-18)
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	Table 4 (p17-18)
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	19-22

1	Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	21
2	Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	22
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4	FUNDING			
5				
6	Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	23
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10 From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097.
11 doi:10.1371/journal.pmed1000097

12 For more information, visit: www.prisma-statement.org.

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BMJ Open

A systematic review of psychosocial needs assessment tools for caregivers of paediatric patients with dermatologic conditions.

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Keywords:	Paediatric dermatology < DERMATOLOGY, Dermatology < INTERNAL MEDICINE, MEDICAL EDUCATION & TRAINING, MENTAL HEALTH, PUBLIC HEALTH, PRIMARY CARE

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Title Page

A systematic review of psychosocial needs assessment tools for caregivers of paediatric patients with dermatologic conditions.

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School of Psychology, Ulster University, Northern Ireland³

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A systematic review of psychosocial needs assessment tools for caregivers of paediatric patients with dermatologic conditions.

ABSTRACT

Background: This review aimed to identify validated dermatology-specific and disease-specific psychosocial needs assessment tools for caregivers of paediatric patients with dermatologic conditions. A secondary objective was to assess the adequacy of their measurement properties.

Methods: Eligible studies involved adult caregivers caring for a child (no age limit) with any form of any skin condition. Predetermined exclusion criteria, as per protocol, were applied to the search results. EMBASE, PsycINFO, MEDLINE (in Ovid SP), Cochrane, CINAHL EBSCO, U Search and Web of Science were searched (2000 to 05 October 2021). Grey literature, bibliographies, online databases of QoL tools and several trial registers were searched (2000 to 05 Oct 2021). Title, abstract, full-text screening, and data abstraction (standardised forms) were done independently in duplicate. Both’s predefined methodological criteria assessed risk of bias. Narrative synthesis was used to present the findings.

Results: 187 full-text articles were examined from a total of 8979 records. Most tools were generic QoL tools, relevant to spouse/partner or based on their child’s perception of the disease or assessed patients’ quality of life. Following quality appraisal, 26 articles were identified, and 11 tools (one dermatology-specific and ten disease-specific) were included. Study-specific, questionnaire-specific and information relating to the adequacy of their measurement properties is provided for each tool. No literature was found pertaining to the use of these tools within healthcare settings and/or as e-tools.

Discussion: With limited evidence supporting the quality of their methodological and measurement properties, this review will promote caregiver health outcomes by informing evidence-based clinical decisions. With increasing demand on limited and valuable healthcare resources, there is justification to develop an accessible solution-focused psychosocial needs assessment e-tool which enables clinicians to identify and triage unmet need.

Funding: Bamford Centre for Mental Health and Wellbeing (Ulster University). Award/Grant number is not applicable.

Registration: PROSPERO (CRD42019159956). COMET Database.

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Strengths and limitations of this study

- The first systematic review to provide a comprehensive overview of psychosocial assessment tools validated for use among dermatological caregivers of paediatric patients.
- This study was conducted with the involvement of a health and life subject-specific librarian and an international multi-disciplinary expert group.
- The protocol was registered on the PROSPERO database (CRD42019159956), the COMET database and was conducted according to the recommendations from the PRISMA statement and ENTREQ statement.
- Adequacy of measurement properties was assessed using Both *et al*'s criteria
- Included articles were limited to being published in English between 2000-2021.

INTRODUCTION

Paediatric dermatology is a unique speciality in that children with lifelong and life-limiting skin disorders are increasingly being cared for by caregivers at home¹, which requires considerable cognitive, emotional, and physical resources.² Skin disease is the fourth leading causes of global disease burden with associated prevalence, care requirements and costs comparable with other diseases, such as cardiovascular disease and diabetes.³⁻⁵ Delayed identification of dermatological caregiver needs and provision of timely supports can seriously compromise the long-term psychosocial wellbeing of caregivers⁶⁻¹⁰ and particularly undermine the care and treatment of paediatric patients affected by rare or chronic skin disease.¹¹ Caregivers of skin disease requires similar systems of monitoring and integrated biopsychosocial support as other comparable chronic conditions.

The World Health Organisation (WHO) directive,¹² recent international guidelines^{13,14} and reports^{9,15-16} emphasise the importance of identifying psychosocial needs assessment tools for use among long-term caregivers, particularly self-referral models. Timely and appropriate identification of caregivers' unmet psychosocial needs has the potential to reduce caregiver strain and increase their ability to provide quality care within the home at reduced public health cost. Although a psychosocial needs assessment could be considered preventative in nature, by anticipating caregiver burnout and decreasing the need for emergency interventions, there is a lack of evidence regarding the use of caregiver assessment tools within healthcare settings. To date, no comprehensive review of psychosocial needs assessment tools validated for use among informal dermatological caregivers of paediatric patients has been conducted. With increasing competition for valuable healthcare resources and services, there is an urgent need to reconceptualise global burden within the construct of 'prevention is better than cure' by informing evidence-based decisions and promoting caregiver health outcomes within day-to-day clinical practice.

Objectives: This review aimed to improve clinician access to existing dermatology-specific and disease-specific psychosocial needs assessment tools, validated for use among caregivers of paediatric patients with dermatologic conditions. Additionally, this review assessed the adequacy of their measurement properties.

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METHODS

This review was conducted according to the recommendations from the PRIMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement.¹⁷ The ENTREQ statement was read and guided in reporting the synthesis of the findings.¹⁸

Eligibility criteria

Studies which involved adult caregivers (age 18 years and over) caring for a child (no age limit) with any form of any skin condition were included. Predetermined exclusion criteria were adhered to (see revised protocol). Included articles were limited to being published in English between 01 January 2000 to 05 October 2021. This ensured that relevant assessment tools developed in the years before publication of the 2017 review¹⁹ were included as that review had limited their search to one database and quality-of-life measures only, which contrasts with the measures recommended by the Cochrane Skin Centre of Evidence Based Dermatology.

Information sources

MEDLINE, PsycINFO and EMBASE (OVID interface) and CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature) were searched (01 January 2000 to 05 October 2021). Grey literature, bibliographies, online databases of QoL tools and several trial registers were also searched (01 January 2000 to 05 October 2021). A ‘snowball’ search was carried out to identify additional studies by manually searching the reference lists of all publications eligible for full-text review. The PRISMA flow diagram (Fig. 1) includes the number of records identified from each source.

Search strategy

One known relevant systematic review¹⁹ was used as a starting point to identify records. A draft search strategy was developed by using candidate search terms that were identified in the titles, abstracts, and subject indexing of that systematic review. The full search strategy development process is included in Supplementary file 1. This strategy was tailored to the specifications of each of the databases searched and developed in collaboration with a subject-specific librarian (J.A.) and expert group. Each tailored database search strategy is

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3 included in Supplementary file 2. All search terms/categories used to search within the
4 supplementary sources are included in Supplementary file 3.
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7 8 **Selection and data collection process** 9

10 Title, abstract and full-text screening were conducted manually in duplicate (independently)
11 by two reviewers (C.W. and G.L.). Extracted data from full-text articles was processed using
12 three standardised extraction forms: (i) Study-specific information included the name of the
13 tool, country of origin, disease of affected patients, sample sizes used in each stage of its
14 development and study setting (ii) Questionnaire-specific information included the domains
15 measured, number of items and subscales, recall period, scoring system, respondent
16 feedback and administration mode and time (iii) Adequacy of measurement properties was
17 evaluated using five methodological domains: validity, reliability, structure, interpretability,
18 and transferability. At the full text screening stage, any discrepancies were resolved by
19 discussion and, where necessary, the third author (M.Mc.L) was consulted.
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29 **Risk of bias assessment** 30

31 Risk of bias in the included studies was assessed independently by two reviewers using Both
32 *et al's*²⁰ criteria, made possible by the similarities between the studies. Each methodological
33 domain and item were graded for risk of bias using predefined criteria. Any discrepancies
34 were resolved by consensus discussions (C.W., G.L.) and, where necessary, by deferment to
35 the third author (M.Mc.L). No overall risk of bias judgment that summarised across domains
36 was given due to the wide variation in assessment across domains within each tool. To
37 improve the robustness of the synthesis and facilitate replicability,²¹ an overview of the
38 domain definitions, items, effect measures, grades and criteria used in assessing the risk of
39 bias is provided in Supplementary file 4.
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49 **Synthesis methods** 50

51 In line with synthesis guidelines,²² a narrative approach was used to arrange the results into
52 two categories: dermatology- and disease-specific tools psychosocial needs assessment
53 tools. To ease identification of variability between and within the included tools, results
54 were also tabulated using the subheadings used in each of the three data extraction forms.
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Certainty assessment

The robust search strategy was validated in MEDLINE when it successfully identified the one known systematic review¹⁹ as part of the search strategy development process (Supplementary file 1). Two authors (C.W. and G.L.) independently assessed the certainty of evidence by assessing risk of bias using a predefined checklist of criteria.²⁰

Patient and Public Involvement (PPI)

An international multi-disciplinary expert group (n=15), including affected adults, clinical psychologists, consultant dermatologists, health policy advisors and caregivers, was established at the outset of the project (September 2017). Ethical approval for this review was obtained from University of Ulster Research Ethics Committee (Ref: REC/20/0004). Informed consent was obtained from all participating members. Anonymity remains protected due to their ongoing involvement in another follow-on study. The Guidance for Reporting Involvement of Patients and the Public (GRIPP) Short Form checklist was used to improve the reporting of PPI in our study.²³ PPI helped identify the research question, guide in terms of review design (search strategy, inclusion and exclusion criteria and data extraction subheadings) and improve the dissemination of findings (invitations to poster and orally present at international dermatology and psychology conferences).

RESULTS

This review identified 8979 records: 8256 records from database searching and 723 records from supplementary sources. After duplicates were removed (n=2577), 6402 records were available. Of the 6402 titles screened, 992 abstracts were screened, and 187 full text articles were assessed for eligibility. This included 15 records identified from the one known systematic review. Of the 187 full text articles assessed for eligibility, 161 records were excluded for reasons which met the exclusion criteria (PRISMA Flow Diagram Fig. 1). No full text records were included after snowballing reference lists (48 screened).

To improve transparency, summaries of the records identified during the initial and updated searches, for both databases and supplementary sources, are included in Supplementary files 3 and 5. PRISMA flow diagrams are included for both the initial search (01 Jan 2000 to

01 April 2020) [Supplementary file 5 (Fig.1)] and updated search periods (01 April 2020 to 05 October 2020) [Supplementary file 5 (Fig.2)] and provide a breakdown of the number of records identified for each database and supplementary source. The two full text articles, identified in the updated search, were both excluded when assessed for eligibility. One record²⁴ contained psychometric data resulting from a biased study design and statistical analysis ('validity was established in a limited range of subjects', 'the parents that responded to the survey were all mothers', 'single-institution cross-sectional study in Japan targeting parents of first-time patients less than 7 years old'). The other record²⁵ identified the Family Dermatology Life Quality Index (FDLQI), which was already identified in the initial search.

The majority of existing, validated dermatological assessment tools identified were generic quality of life (QoL) tools and/or assess the patients' quality of life. Of those tools validated for use among caregivers, most were either relevant to spouse/partner or depend on the caregiver to complete but are based on their child's perception of the disease (Fig. 1). Very few needs assessment tools were validated for use among caregivers of paediatric patients affected with dermatologic disease. In summary, a total of 11 assessment tools were identified from the 26 articles included in this review.²⁶⁻³⁶ Ten disease-specific assessment tools were identified (**PFI-15**²⁶, **Family Pso**²⁷, **QPCAD**²⁸, **CADIS**²⁹, **PIQoL-AD**³⁰, **DFI**³¹, **PASECI**³², **CarGOQoL**³³, **EB-BoD**³⁴ and **FBI**³⁵) and one dermatology-specific assessment tool was identified (**FDLQ**³⁶). Table 1 provides a summary of study-specific information and includes the name of tool, country of origin, disease of affected patient, sample sizes and study setting. Table 2 summarises questionnaire-specific information under the subheadings domains, subscales, number of items, recall period, scoring system and administration time. Table 3 provides an overview of the adequacy of the measurement properties of the included tools, including transferability, reliability, validity, structural and interpretability. Table 4 provides a graded risk of bias assessment (using the predefined criteria) of each methodological domain and item for each of the eleven tools.

Disease-specific needs assessment tools

The Family Psoriasis Index (PFI-15)²⁶ is recommended for use alongside a dermatology-specific tool. As it is assessed on current time only it does not rely on accurate recall. However, due to the small sample size, factor analysis could not be done and there is a lack

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of comparison of PFI scores with other generic family QoL scales. In order to achieve its Cronbach alpha value (0.86), it was necessary to delete five items. It has a weaker focus on the emotional aspects of living with affected members. Those accompanying patients to the primary care centre and inpatients were not included in the creation of the PFI, which restricts the generalisation of the quantitative findings.

The Family Pso²⁷ was created from interviews (n=95) with psoriasis patients and their family members. Three experts (no caregiver involvement) decided the generation items for piloting and item reduction. Other limitations include that a small sample was used in its testing and were predominantly female partners of the interviewees. Its advantages include that the wording is more focused on emotional aspects of caregiving as opposed to HR-QoL.

Four tools were found that assess the impact of atopic dermatitis on the family. The **Quality of life in Primary Caregivers of Children with Atopic Dermatitis (QPCAD)**²⁸ has a one week recall and has been validated for use among primary caregivers of children with AD in the Japanese version only. Convergent validity requires further study and only caregivers of mild and moderate patients from an urban area were included in the study.

The **Childhood Atopic Dermatitis Impact Scale (CADIS)**²⁹ is validated for use with both patients and parents of patients younger than six years. Rasch analysis reduced the tool to a 45-item version which is responsive to clinical change in AD.

The **Parents' Index of Quality of Life in Atopic Dermatitis (PIQoL-AD)**³⁰ assesses the impact of AD on caregivers of affected children, aged eight years or younger. The PIQoL-AD adopts a dichotomous response system which is less sensitive to subtle changes in HR-QoL and includes only items that considers the negative aspects of psychological well-being.

The **Dermatitis Family Impact (DFI)**³¹ tool is the tool most widely reported in studies, having been used in over 750 clinical trials, although often at longer intervals despite being validated for use with a one-week recall period. As most of DFI studies are in secondary care hospitals, there exists the possibility of maximising the chances of the DFI scores showing significant improvements following an intervention.³¹ Dodington's review³⁷ found that internal consistency and test-retest reliability was adequately demonstrated, but highlighted that psychometric measures were less well established due to a lack of vigour in both the creation and validation processes. No valid score-banding descriptors of DFI score

meanings are included and no information to establish the MCID of DFI score is available.³¹
No studies demonstrated dimensionality, factor structure or differential item functioning.

The final tool included in this review was the **Parental Self-Efficacy with Eczema Care Index (PASECI)**³². It is a generalised self-efficacy scale focusing on the management of four subscales: medication, symptoms, personal challenges, and communication with healthcare teams. It has a two-factor structure which considers the performance of routine management tasks and the management of child symptoms and behaviour. There was reliance on self-reported data, potentially affecting the fidelity of the results. More research is needed on banding and categorisation.

Validation of **The CareGiver Oncology Quality of Life (CarGOQoL)**³³ was carried out using dermatology experts other than caregivers. Several non-optimal indicators of validity are indicated in Table 4.

The **Epidermolysis Bullosa – Burden of Disease (EB-BoD)**³⁴ tool needed to remove non-discriminatory items, such as frustration and guilt, from the original FBI³⁸ during its creation. It requires further validation in larger EB patient and/or caregiver groups before being revalidated for use in other languages and cultures.

The Family Burden of Ichthyosis (FBI)³⁵ is the only validated disease-specific questionnaire which measures the concept of burden for ichthyosis caregivers. The monocentric study used parents and their affected children in the creation of verbatim using an unnamed French social assessment, which could not be accessed for this review. Selection bias was a possibility as 40% of participants cared for those affected by severe forms of ichthyosis (severity score 50 or greater). Limitations include that validation of the FBI was carried out using parents of children affected with only the severest forms of ichthyosis. Although itch is one of the significant challenges named by parents of children affected with ichthyosis (third most significant impact during the validation of the DFI³¹), it does not feature as an item. Similarly, no items relate to pain in the finalised FBI.³⁵ Verification of its psychometric properties, preferably in a multicentre study is required. Caregiver feedback included that the finalised generation items were negatively phrased. The original French questionnaire has been linguistically and culturally adopted in Italy.³⁸

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Dermatology-specific needs assessment tools

The **Family Dermatology Life Quality Index (FDLQI)**³⁶ is the most used dermatology-specific HR-QoL. The psychosocial impact loaded six items (emotional impact, physical wellbeing, impact on relationships, leisure, social life, and people’s reactions) and the physical impact loaded four items (burden, effect on job/study, household expenditure and housework). Fifty semi-structured interviews took place with informed the items generated for testing during piloting. The feedback (n=59 items) from these interviews has been termed ‘the greater concept’. Piloting of the 19 items occurred with 20 parents or partners of those originally interviewed, potentially introducing bias. Limitations include that the life-course of skin disease is not reflected in the FDLQI and that it depends on recall accuracy. Definitions, such as MID and the meaning of FDLQI scores are missing and future research is required to show the unidimensionality of the tool. The FDLQI was not tested for responsiveness for clinical change in a hospital or intervention context. Several items cannot discriminate between inflammatory and uninflammatory groups.

One common theme which emerged was the variation in methodological rigor used in measuring informal dermatological caregiver needs. Using the risk of bias assessment, each of the reviewed tools indicated an incomplete psychometric overview meaning that the generalisability and interpretation of results remain limited. Each reviewed tool (11 of 11; 100%) evaluated four or more psychometric properties. They do not comply with the OMERACT filter criteria and consequently are unable to be included in the development of a future COS.³⁹

In terms of structure, five tools reported the use of factor analysis.^{27,32-34,36} Three tools reported the use of the more recently developed item response theory (IRT) to determine psychometric properties.^{26,29,30} Other tools neither reported factor analysis or IRT.^{28,31,35} Apart from two tools reporting strong item bias,^{26,30} the other nine tools^{27-29,31,32-35,36} reported weak item bias. One tool³¹ reported the use of distribution-based categorisation techniques, but the other ten tools did not report on categorisation. MCID was not reported for any tool other than one.³⁰

In terms of reliability, all tools reported a high internal consistency (IC>0.95). Two tools did not report their retest reliability.^{27,35} One reported a weak retest reliability³³ (ICC<0.70),

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3 while the other eight tools reported a good retest reliability^{26,28-32,34,36} (ICC>0.70). In terms
4 of conceptual validity, four tools have less well-balanced domains.^{28-30,33} The other seven
5 tools include well balanced domains.^{26,27,31,32,34-36} No information is given regarding the
6 construct validity for one tool.²⁷ Five tools demonstrate that <75% of results are in
7 accordance with their hypothesis^{31,32-35} and five tools demonstrate that >75% of results are
8 in accordance with their hypothesis.^{26,28-30,35} The majority of tools demonstrate poor
9 convergent validity apart from two^{31,32} (>0.70). The PFI-15 provides no information on
10 convergent validity.³⁶ The other eight tools in this review show a convergent validity value
11 of <0.70.^{27-30,33-36}

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Table 1: Study-specific Information relevant to included assessment tools

References of included publications (first author, year, reference)	Country of Origin	Disease of affected patients	Name of Measurement Instrument	Sample size (n)	Study setting
Eghlileb et al ²⁶ (2009)	United Kingdom (UK)	Psoriasis	Psoriasis Family Index (PFI-15)	Interviews (Unknown)	Monocentric Outpatient clinic
Mrowietz et al ²⁷ (2017)	Germany	Psoriasis	Family Pso QoL in Primary Caregivers of children with Atopic Dermatitis (QPCAD)	Interviews (14) Piloting (96) Validation (96)	Monocentric Outpatient clinic
Kondo-Endo et al ²⁸ (2009)	Japan	Atopic Dermatitis	Childhood Atopic Dermatitis Impact Scale (CADIS)	Interviews (unknown) Pilot (33) Validation (400)	Monocentric Outpatient clinic
Chamlin et al ²⁹ (2005)	United States of America (USA)	Atopic Dermatitis	Parent's Index QoL - Atopic Dermatitis (PIQoL-AD)	Interviews (unknown) Piloting (20) Validation (300)	Two dermatology paediatric practices (San Francisco & Chicago)
McKenna et al ³⁰ (2005)	UK, Netherlands, Italy, Spain, USA, Switzerland, Germany, France (simultaneous development)	Atopic Dermatitis	Dermatitis Family Impact (DFI)	Interviews (65) Piloting (140 total) Validation (ranged between countries 45-328)	Monocentric Outpatient clinic
Lawson et al ³¹ (1998)	UK	Dermatitis		Interviews (29) & Focus Groups (10) Piloting (14) Validation (56)	Monocentric Outpatient clinic

Continued

References of included publications (first author, year, reference)	Country of Origin	Disease of affected patients	Name of Measurement Instrument	Sample size (n)	Study setting
Ersser et al ³² (2015)	UK	Eczema	Parental Self-Efficacy with Eczema Care Index (PASECI)	Literature review-generation items Piloting & Validation (242)	Monocentric Outpatient clinic
Minaya et al ³³ (2012)	France	Skin cancer	CareGiver Oncology Quality of Life (CarGOQoL)	Interviews (77) Piloting (837) Validation (unknown)	Monocentric Outpatient clinic
Dufresne et al ³⁴ (2015)	France	Epidermolysis Bullosa	Epidermolysis Bullosa - Burden of Disease (EB-BOD)	Complaints (23) informed item generation Piloting (Lionbridge institution) Validation (55)	Monocentric Outpatient clinic
Dufresne et al ³⁵ (2013)	France	Ichthyosis	Family Burden Ichthyosis (FBI)	Interviews (94) Piloting (42) Validation (30)	Monocentric Outpatient clinic
Basra et al ³⁶ (2008)	UK	All - general dermatology instrument	Family Dermatology Life Quality Index (FDLQI)	Interviews (50) Piloting (20) Validation (14)	Monocentric Outpatient clinic

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Table 2: Questionnaire-specific information relevant to included assessment tools

Name of Measurement Instrument	Domains measured	Number of items and subscales	Recall Period	Scoring system	Respondent Feedback	Admin Mode (Time in minutes)
Psoriasis Family Index (PFI-15) ²⁶	Social Life, Leisure activities Sporting activities, People's reactions, Worry about future Housework, Relationships Treatment duration, Clothing Shopping, Sleep	15 items	Now	4-point scale (0-3)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (2)
Family Pso ²⁷	Emotional Domain-emotional impact. Social Domain -Impact on daily activities & work /school and treatment. Leisure Domain - Influence on leisure/ personal relationships	15 items	1 month	5-point Likert format (0-4) and 'Does not apply'	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (3)
QoL in Primary Caregivers of children with Atopic Dermatitis (QPCAD) ²⁸	Achievement (3) Worry (6) Family co-operation (3) Exhaustion (8)	19 items	Past week	5-point scale (none to extremely)	Brief in length Moderate to administer, score and interpret Conflicting evidence of alternative forms	Self-report (unknown)
Childhood Atopic Dermatitis Impact Scale (CADIS) ²⁹	Impact on family (3 domains) Sleep and emotions Family & social function	45 items	1 month	5-point scale (never to all the time)	Long in length and problems of acceptability Moderate to administer, score and interpret Absent evidence of alternative forms	Self-administered (6)

Continued

Name of Measurement Instrument	Domains measured	Number of items and subscales	Recall Period	Scoring system	Respondent Feedback	Admin Mode (Time in minutes)
Parent's Index QoL - Atopic Dermatitis (PIQoL-AD) ³⁰	1 domain - needs that can be influenced by a child with a diagnosis of AD	28 items	Not reported	5-point scale (never to all the time)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (3)
Dermatitis Family Impact (DFI) ³¹	Personal relationships and helping with treatment, Food and feeding, Sleep, Housework Shopping, Financial, Leisure Tiredness, Emotional distress	10 items	1 week	4-point scale (not at all, a little, a lot, very much)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (unknown)
Parental Self-Efficacy with Eczema Care Index (PASECI) ³²	Managing medications Managing eczema & symptoms Communication with Healthcare teams Managing Personal challenges	29 items 4 subscales	1-week pre and 4 weeks post intervention	11-point Likert Scale	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Clinician administered (3)
CareGiver Oncology Quality of Life questionnaire (CarGOQoL) ³³	Psychological well-being, Burden, Relationship with health care, Administration and finances, Coping, Physical well-being, Self-esteem, Leisure time Social support and private life	29 items	1 week	5-point Likert scale (never/not at all, rarely/a little, sometimes/somewhat, often/a lot, always/very much)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (3)
Epidermolysis Bullosa - Burden of Disease (EB-BOD) ³⁴	Economic and Social impact (5) Family Life (7) Disease & Treatment (5) Child's Life (3)	20 items	Not stated	7- point scale (always, very often, often, sometimes, rarely, never, not applicable)	Moderate to administer, score and interpret Absent evidence of alternative forms Long in length and problems of acceptability	Self-administered (unknown) Continued

Name of Measurement Instrument	Domains measured	Number of items and subscales	Recall Period	Scoring system	Respondent Feedback	Admin (Time in minutes)	Mode in
Family Burden Ichthyosis (FBI) ³⁵	Work & Psychological impact, Daily Life, Pain, Familial and Personal Relationships	25 items	Not stated	4-point scale (definitely yes, maybe, definitely not, I don't know)	Long in length and problems of acceptability Moderate to administer, score and interpret	Self-administered (3)	
Family Dermatology Life Quality Index (FDLQI) ³⁶	Housework & expenditure Emotional & Physical wellbeing Impact on study/job, Social Life Burden of care, Leisure Activities	10 items	1 month	4-point scale (not at all/not applicable, a little, quite a lot, very much)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (3)	

Table 3: Adequacy of the measurement properties relevant to included assessment tools with excellent and good methodological quality

Name of Measurement Instrument	Transferability	Reliability	Validity	Structure	Interpretability
Psoriasis Family Index (PFI-15) ²⁶	Sometimes translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - well balanced domains Construct >75% results in accordance with hypothesis Convergent - No information	IRT Weak sensitivity to detect changes Strong item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
Family Pso ²⁷	Never translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC not reported or correlation coefficient <0.70	Conceptual - more focused on objective/subjective domains Construct - no information Convergent <0.70	Factor analysis Weak sensitivity to detect changes Weak item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
QoL in Primary Caregivers of children with Atopic Dermatitis (QPCAD) ²⁸	Never translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - more focused on objective/subjective domains Construct <75% results in accordance with hypothesis Convergent <0.70	Satisfactory response to change in disease severity Satisfactory test-retest reliability	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
Childhood Atopic Dermatitis Impact Scale (CADIS) ²⁹	Sometimes translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - well balanced domains Construct >75% results in accordance with hypothesis Convergent <0.70	IRT Strong sensitivity to detect changes Weak item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
Parent's Index QoL - Atopic Dermatitis (PIQoL-AD) ³⁰	Always translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - more focused on objective/subjective domains Construct >75% results in accordance with hypothesis Convergent <0.70	IRT Strong sensitivity to detect changes item bias Strong item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - known in heterogeneous sample

						Norms - General nor dermatology patients
		Always translated using guidelines	IC: 0.95 > Cronbach's α >0.70	Conceptual - well balanced Construct <75% results in accordance with hypothesis Convergent >0.70	No factor analysis or IRT Strong sensitivity to detect changes Weak item bias	Categorisation - used distribution-based techniques MCID - not reported
Dermatitis Family Impact (DFI) ³¹	Sometimes analysed in a cultural equivalence study		Retest reliability: k or ICC >0.70			
Parental Self-Efficacy with Eczema Care Index (PASECI) ³²	Always translated using guidelines	IC: 0.95 > Cronbach's α >0.70	Conceptual - well balanced Construct <75% results in accordance with hypothesis Convergent >0.70	Factor analysis Satisfactory response to change in disease severity Weak item bias		Norms - General nor dermatology patients
	Never analysed in a cultural equivalence study	Retest reliability: k or ICC >0.70				Categorisation - not reported MCID - not reported
CareGiver Oncology Quality of Life Questionnaire (CarGOQoL) ³³	Sometimes translated using guidelines	IC: 0.95 > Cronbach's α >0.70	Conceptual - more focused on objective/subjective domains Construct <75% results in accordance with hypothesis Convergent <0.70	Factor analysis Low / moderate sensitivity to changes Weak item bias		Norms - General nor dermatology patients
	Never analysed in a cultural equivalence study	Retest reliability: k or ICC <0.70				Categorisation - used distribution- based techniques MCID - not reported
Epidermolysis Bullosa - Burden of Disease (EB-BOD) ³⁴	Sometimes translated using guidelines	IC: 0.95 > Cronbach's α >0.70	Conceptual - well balanced Construct <75% results in accordance with hypothesis Convergent <0.70	Factor analysis Weak sensitivity to detect changes Weak item bias		Norms - General nor dermatology patients
	Never analysed in a cultural equivalence study	Retest reliability: k or ICC >0.70				Categorisation - not reported MCID - not reported
		IC: 0.95 > Cronbach's α >0.70				
Family Burden Ichthyosis (FBI) ³⁵	Sometimes translated using guidelines	Retest reliability: k or ICC not reported or correlation coefficient <0.70	Conceptual - well balanced Construct <75% results in accordance with hypothesis Convergent <0.70	No factor analysis or IRT Weak sensitivity to detect changes Weak item bias		Norms - General nor dermatology patients
	Never analysed in a cultural equivalence study					Categorisation - not reported MCID - not reported
Family Dermatology Life Quality Index (FDLQI) ³⁶	Always translated using guidelines	IC: 0.95 > Cronbach's α >0.70	Conceptual - well balanced domains Construct >75% results in accordance with hypothesis Convergent <0.70	Factor analysis Strong sensitivity to detect changes Weak item bias		Norms - General nor dermatology patients
	Never analysed in a cultural equivalence study	Retest reliability: k or ICC >0.70				Categorisation - not reported MCID - not reported

Legend: IRT, item response theory; IC, internal consistency; ICC, intraclass correlation coefficient; MCID, minimal clinically important difference.

Table 4. Evaluation of disease-specific and dermatology-specific tools (Risk of bias assessment criteria outlined in Supplementary file 4)

Criteria	PFI-15 ²⁶	Family Pso ²⁷	QPCAD ²⁸	CADIS ²⁹	PiQoL-AD ³⁰	DFI ³¹	PASECI ³²	CarGOQoL ³³	EB-BoD ³⁴	FBI ³⁵	FDLQI ³⁶
Validity											
Conceptual	A	B	B	A	B	A	A	B	A	A	A
Construct	A	C	B	A	A	B	B	B	B	B	A
Convergent	B	B	B	B	B	A	A	B	B	B	B
Interpretability											
Norms	C	C	C	C	C	C	C	C	C	C	C
Categorization	C	C	C	C	C	B	C	B	C	C	C
MCID	C	C	C	C	A	C	C	C	C	C	C
Reliability											
Internal consistency	A	A	B	A	A	A	A	A	A	A	A
Retest reliability	A	C	A	A	A	A	A	C	A	C	A ¹
Structure	A	B	B	A	A	C	B	C	B	C	B
Responsiveness	C	C	B	A	A	A	B	C	C	A	A
Item bias	A	C	C	C	A	C	C	C	C	C	C
Cultural issues											
Translations	B	C	C	B	A	A	A	B	B	B	A
Cultural equivalence	C	C	C	C	C	B	C	C	C	C	C
Respondent burden	A	A	A	B	A	A	B	B	B	B	A
Administrative burden	A	A	B	B	A	A	B	B	B	B	A
Alternative forms	C	C	B	C	C	C	C	C	C	C	C

Legend: PFI-15, The Family Psoriasis Index; Family Pso, Family Psoriasis; QPCAD, QoL in primary caregivers of children with atopic dermatitis; CADIS, Childhood Atopic Dermatitis Impact Scale; PiQoL-AD, Parents' Index QoL Atopic Dermatitis; DFI, Dermatitis Family Index; PASECI, Parental Self-Efficacy with Eczema Care Index; CarGOQoL, The CareGiver Oncology Quality of Life; EB-BoD, Epidermolysis Bullosa Burden of Disease; FBI, Family Burden Ichthyosis; FDLQI, Family Dermatology Life Quality Index; MCID, minimal clinically important difference; ¹ Objective and subjective domains are described by Muldoon et al (1998).

DISCUSSION

This is the first systematic review to address gaps in the existing evidence base around the identification of appropriate psychosocial needs assessment for caregivers of paediatric patients with dermatologic conditions. This topic represents an emerging area for which there is a lack of up-to-date good quality synthesised evidence. With increasing numbers of paediatric patients of chronic skin disease being cared for by informal caregivers, often with limited medical training, key international multi-disciplinary stakeholders (including clinicians, dermatological caregivers, and policymakers) emphasised an urgent need to improve clinician awareness of existing needs assessment tools, to help them make informed evidence-based decisions relating to assessment. The need to promote caregiver health outcomes within day-to-day clinical practice has become even more significant during Covid-19, a period of enhanced social isolation and increased caregiver hypervigilance and burnout.

This review identified eleven psychosocial needs assessment tools validated for use among caregivers of paediatric patients with dermatologic conditions. A narrative approach was used to arrange the reviewed tools into two groups: dermatology-specific and disease-specific tools. To ease identification of risk of bias, study variability and measurement properties between and within the included tools, results were additionally tabulated using the predefined subheadings on the data extraction forms.

Although skin disease may be characterised at times by unpredictable episodes in symptom severity,^{33,34,36} that requires similar systems of monitoring and integrated biopsychosocial support as other chronic conditions,^{5,40} our review highlights the lack of literature pertaining to the use of these assessment tools in healthcare settings. This review suggests that the mismatch between the recognised impact of caregiving for skin disease and the failure of practitioners to effectively engage with its management may be attributed to the biomedical model of assessment reflected in existing tools.

In contrast to the tools reviewed,²⁶⁻³⁶ which utilized measures of other constructs as a proxy for caregivers' need, it appears vital to directly assess informal dermatological caregivers' needs (at problem area and support level) and plan for how that knowledge will be used to help support these needs.⁴¹⁻⁴³ Similarly, future assessments should use the scope of the

International Classification of Functioning, disability, and health (ICF)⁴⁴ to inform their caregiver framework in terms of contextual factors and in terms of functioning and disability. Despite the recognised difficulty of assessing chronic pathologies by clinical or quality of life (QoL) aspects alone,^{45,46} most tools identified in this review were generic QoL tools. The European Academy of Dermatology and Venereology (EADV) Quality of life task force,⁴⁷ Cochrane Skin Centre of Evidence Based Dermatology⁴⁸ and the Harmonising Outcome Measures for Eczema (HOME) initiative³⁹ reinforce that generic QoL assessments do not encompass the many factors that contribute to the psychosocial burden of skin disease⁴⁹ and are not as sensitive, responsive, or relevant to individual patients or their caregivers.⁵⁰

We considered appropriate measurement tools to be theoretically driven, rigorously conceptualized with input from caregivers at each stage, consider disease life-course, tested for validity and reliability and intended to assess caregiver needs in relevant settings.^{39,41,47,48} Conceptual and theoretical work on dermatological caregivers' needs could have been relatively lacking because of the varying degree by which the tools were informed by caregiver experience, with minimal description of the questionnaire development process, absence of or exclusionary key definitions such as family, caregiver and domain and participants were not asked to clarify their relationship to the patient attending the outpatient clinics. Some of the tools only included items for the negative aspect of psychological wellbeing.^{31,35,36}

Healthcare teams require access to validated assessment tools which considers all dimensions along the care continuum and which do not use measures of other constructs as a proxy for caregivers' needs⁵¹ to provide culturally sensitive care. An international multicentric approach could best address variables including culture, demographics and disease severity. Although none of the reviewed assessment tools allow for the assessment of disease variables, including disease severity, we recommend that future needs assessment tools include disease parameters when designing their assessment framework. Dufresne³⁵ found that increased disease severity led to increased caregiver burden, suggesting that tools which assess factors relevant to clinical severity of disease could better inform the types of supports needed long-term.

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Future assessment should be practical and feasible for daily use within busy clinics. A self-reporting psychosocial needs assessment e-tool, developed to identify caregiver needs (at both problem and support level), could best serve to address non-clinical barriers to assessment including lack of time, support staff and easy tools and reduce the reported high rates of non-use of validated tools within daily practice.⁵² Research reinforces improved care recipient and caregiver outcomes⁴¹⁻⁴⁴ when caregivers are facilitated to regularly self-report perceived needs enabling clinicians to identify and/or triage unmet psychosocial care needs.

Strengths and Limitations:

Strengths include a published protocol, a multi-disciplinary expert group and health science librarian involved in the design of the review, a comprehensive literature search, information provision on study, questionnaire, measurement properties and risk of bias. This review also provides key recommendations for future research. Although time was needed to ensure that members were involved as equal partners in debates and decisions around key issues, benefits of PPI included having experts with lived experience who creatively contributed towards the methodology. Limitations included studies published in the English language between 2000-2021.

To enhance the chances of developing a truer set of outcome domains for improved Core Outcome Set (COS) uptake, future assessments should adopt a more thorough typology to assess the degree to which deficits in caregivers' needs are present and to develop transparent conceptual frameworks which include key definitions and which are built upon a hybrid model using good quality caregiver frameworks alongside qualitative feedback from large and culturally diverse international cohorts of caregivers.⁵³ With increased emphasis on e-healthcare, it seems both desirable and practical to conceptualise an accessible and solution-based model of future assessment which can address recognised healthcare challenges, including limited clinic time, poor caregiver identification and healthcare communication,⁵³⁻⁵⁸ allowing for timely identification and/or triage of unmet psychosocial needs by practitioners while strengthening a caregiver's sense of autonomy, coping ability and resilience.^{59,60} To inform the development of solution-focused assessment e-tools, it is important that research is also conducted into which supports are rated as most important by informal dermatological caregivers.

CONCLUSION

Although no gold-standard tool exists for measuring the psychosocial needs of dermatological caregivers, this comprehensive review improves clinician awareness and knowledge of eleven validated psychosocial needs assessment tools for caregivers of paediatric patients with dermatologic conditions. It is hoped that this review will inform the development of solution-based models of assessment e-tools for improved dermatology care coordination. As dermatological caregiving research moves forward with significant public and private investment, rigorous measurement of caregivers' needs is essential for the development of social services, public policies and improved COS uptake. These findings have implications for clinical practice, service development and future research and reinforce that attitude towards caregivers is pivotal in developing assessment for the purpose of accessing supports and services.

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Competing interests Abstract was selected for paper presentation by the European Society for Dermatology & Psychiatry Conference in June 2021. Abstract has also been selected for publication by the British Journal of Dermatology.

Data Sharing statement All data relevant to the study are included in the article or uploaded as a supplementary information file.

Amendments to protocol Revisions to PROSPERO protocol reflect (i) the later initial search start date (to allow for preliminary searches to tailor the comprehensive search strategies) (ii) 19-year search period limit changed to a 21-year search period limit in the inclusion criteria to reflect updated search request (iii) inclusion of Both *et al*'s adequacy of measurement criteria (iv) exclusion criteria updated to include 'assessment tool already identified in initial search'.

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37 [content/uploads/2018/10/eMental-Health-State-of-the-art-Opportunities-for-](https://www.mentalhealthreform.ie/wp-content/uploads/2018/10/eMental-Health-State-of-the-art-Opportunities-for-Ireland-Full-Report.pdf)
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Figure 1 Legend:

PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.; CINAHL, Cumulated Index to Nursing and Allied Health Literature; EBSCO, Elton B. Stephens Company; PsycINFO, Psychological Information Database; U Search, Ulster University Search; PROQOLID, Patient-Reported Outcome and Quality of Life Instruments Database; ISRCTN, International Standard Randomised Controlled Trials Number; UK, United Kingdom; US, United States; EU, European Union; QoL, Quality of Life.

For peer review only

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Figure 1: PRISMA Flow Diagram for search (01 Jan 2000 to 05 Oct 2021)

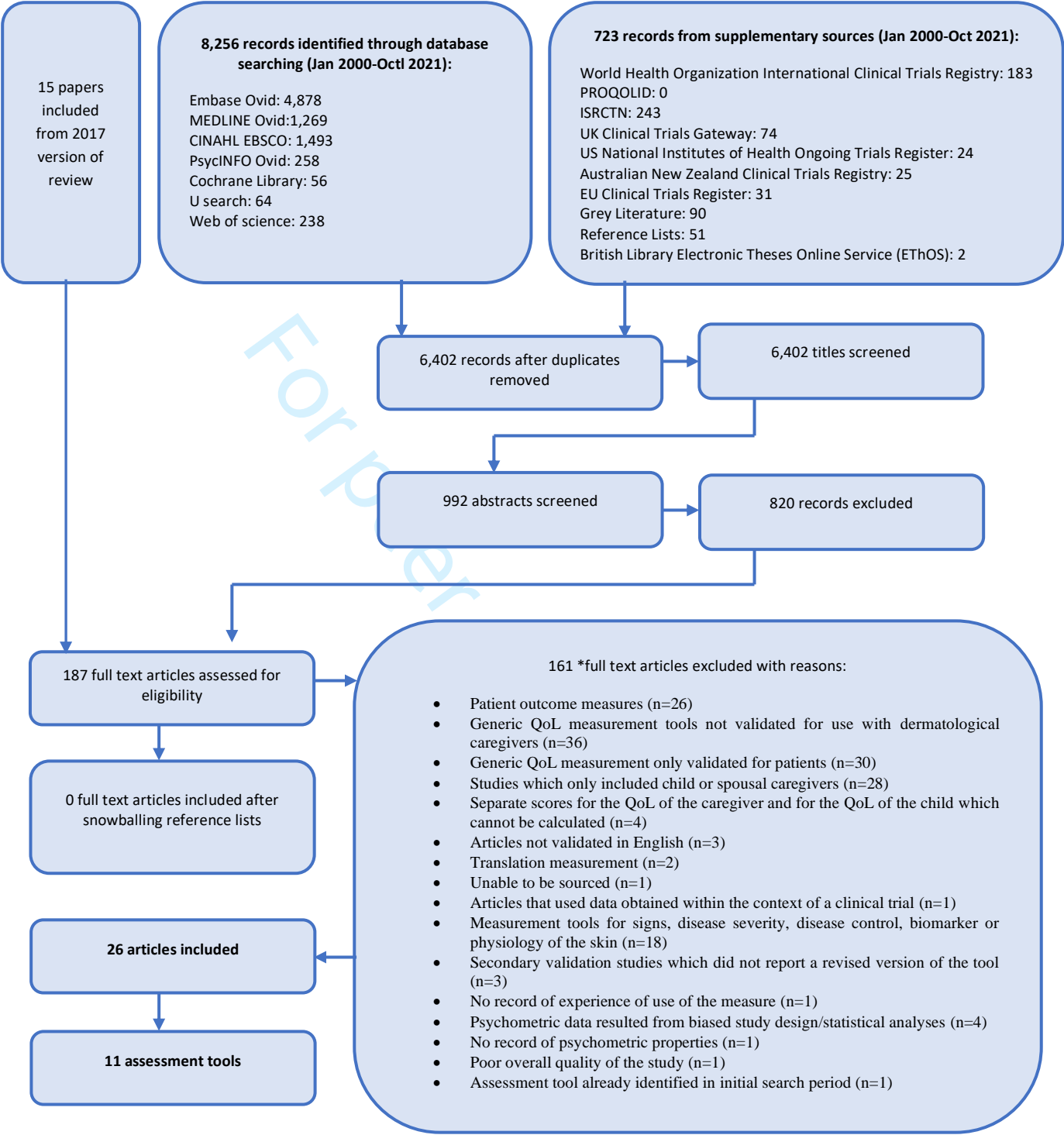


Figure 1 Legend:

PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.; CINAHL, Cumulated Index to Nursing and Allied Health Literature; EBSCO, Elton B. Stephens Company; PsycINFO, Psychological Information Database; U Search, Ulster University Search; PROQOLID, Patient-Reported Outcome and Quality of Life Instruments Database; ISRCTN, International Standard Randomised Controlled Trials Number; UK, United Kingdom; US, United States; EU, European Union; QoL, Quality of Life.

Supplementary file 1: Search Strategy development process

One known relevant systematic review (Sampogna *et al* 2017) was used as a starting point to identify records within databases. A draft search strategy was developed by using candidate search terms that were identified in the titles, abstracts and subject indexing of that systematic review.

Table 1: Preliminary keywords/search terms identified:

Psychosocial or psycho-social or psychodermat* or social or cognit* or emotion* or well-being or psychologic* or adjust* disorder or depress* or anxiety or anxious or coping or stress or mental health or guilt or embarrassment
disease specific or dermatolog* specific or disease burden or burden of disease or scale or needs assessment or psychosocial assessment or index or tool or interview or quality of life or validat* or QoL or measure or impact or screen* or wellbeing or well being or questionnaire or health related quality of life or health profile or inventory or intervention or evaluation or schedule or survey or audit or neuropsychological assessment or activities of daily living or dermatolog* specific health instrument or psychosocial impact or psycho social impact
Caregiver* or family or 'family caregiver' or 'family care giver*' or parent or homecare* or home care* or adult or adults* or grownup* or grown up or families or relative or relation* or mother* or father* or family nurs* or primary care provider* or informal caregiver* or carer* or 'greater patient concept' or homecare
Child or children or infant* or toddler* or baby or babies or youngster* or young pers* or preschool* or teenage* or adolescen* or prematur* or pediatri*
Skin* or skin condition* or skin disorder* or scaliness or keratos* or cornificat* or rare skin dermatology* or chronic disease or chronic condition or long-term condition or chronic illness or incurable or disability or life limiting or long term care or life threatening or palliative or assistive technology or continu* of care or chronic car* or Ichthyos* or continuing car* or impact of chronic skin disease
Skindex or measuring the family impact of dermatological conditions or the family impact of skin diseases

Additional search terms were then identified from the results of that strategy, from the reference list of the systematic review, from systematic searching of each relevant electronic database for relevant "MeSH" terms (included in each search strategy below) and from checking using the PubMed PubReMiner word frequency analysis tool. This strategy was tailored to the specifications of each of the databases searched and developed in collaboration with a subject-specific librarian (J.A.) and expert group. We did not include a specific definition of psychosocial because, given a lack of consensus in the literature on the

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use of this term, we wanted to include a diverse range of tools (cognitive, social and emotional) to answer the research question.

Pre-planned keyword searches were limited to titles and abstracts, with MeSH terms being exploded, where available. Each of the keywords above were individually mapped to appropriate subject headings (MeSH) in each database, where available, to ensure a broad and thorough search. Each concept was taken individually and OR MeSH with the keyword(s). This process was repeated with all five concepts and were AND together at the end. The Cochrane RCT filter (reported in the Cochrane Handbook v5.2) was used in the development of the MEDLINE strategy. Independent peer review, by both first and second author, involved proofreading the overall structure, spelling and syntax. The search strategy was validated in MEDLINE when it successfully identified the one known systematic review and three of five further studies (Finlay, 1997; Ashcroft *et al* 1998; De Korte *et al* 2002; Bennett *et al* 2003; Haywood *et al* 2005; Nemeth, 2006) identified as part of the strategy development process.

As per eligibility criteria, the original search strategy was limited to English language studies and from studies published between 01 January 2000 to 01 April 2020. We searched in MEDLINE, PsycINFO and EMBASE using the OVID interface. CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature) was additionally searched.

Updated searches were conducted on the 5th October 2021 for 01 April 2020 to 5th October 2021 (using original search strategies). The PRISMA flow diagram accounts for this updated search and has been included with this submission (Figure 1).

Supplementary file 2: Database search strategies**Search Strategy for Embase**

1. (Psychosocial or psycho-social or psychodermat* or social or cognit* or emotion* or well-being or psychologic* or adjust* disorder or depress* or anxiety or anxious or coping or stress or mental health or guilt or embarrassment).m_titl.
2. mental disease/
3. behavior/ or cognitive therapy/ or behavior disorder/
4. social participation/ or social support/ or social alienation/ or "social determinants of health"/ or social support assessment/ or social isolation/ or social psychiatry/ or social aspect/ or social network/ or social psychology/ or social isolation stress test/ or social behavior/ or Social Interaction Anxiety Scale/ or social norm/ or social life/ or social interaction/ or Social Support Index/ or social stigma/ or "social aspects and related phenomena"/ or social phobia/ or social acceptance/
5. cognitive behavioral stress management/ or Social Cognitive Theory/ or cognitive therapy/
6. psychosocial care/ or Psychosocial Adjustment to Illness Scale/ or psychosocial disorder/
7. anxiety/ or anxiety assessment/
8. emotion assessment/ or emotion/
9. wellbeing/ or psychological wellbeing assessment/
10. coping behavior/
11. guilt/
12. emotion/
13. depression/ or depression assessment/
14. psychological adjustment/ or adjustment disorder/ or adjustment/ or Psychosocial Adjustment to Illness Scale/
15. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
16. (disease specific or dermatolog* specific or disease burden or burden of disease or scale or needs assessment or psychosocial assessment or index or tool or interview or quality of life or validat* or QoL or measure or impact or screen* or wellbeing or well being or questionnaire or health related quality of life or health profile or assessment* or inventory or intervention or evaluation or schedule or survey or audit or neuropsychological assessment or activities of daily living or dermatolog* specific health instrument or psychosocial impact or psycho social impact).m_titl.
17. disease burden/
18. exp questionnaire/ or exp "quality of life"/
19. clinical assessment tool/
20. psychological interview/ or interview/
21. exp "quality of life"/
22. health impact assessment/
23. exp needs assessment/
24. health survey/ or health care survey/
25. daily life activity/

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- 5 27. clinical assessment tool/
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- 10 adult or adults* or grownup* or grown up or families or relative or relation* or mother* or father* or family
- 11 nurs* or primary care provider* or informal caregiver* or carer or 'greater patient concept' or
- 12 homecare).m_titl
- 13
- 14 30. caregiver burden/ or exp caregiver/ or caregiver support/ or Caregiver Strain Index/
- 15
- 16 31. parent/
- 17
- 18 32. adult/
- 19
- 20 33. home care/
- 21 34. family functioning/ or family coping/ or family life/ or family centered care/ or family stress/ or family
- 22 health/ or exp family assessment/ or exp family/
- 23
- 24 35. relative/
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- 26 36. sibling/
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- 28 37. grandparent/
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- 30 38. 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37
- 31 39. (Ichthyos* or Skin* or skin condition* or skin disorder* or scaliness or keratos* or cornificat* or rare skin
- 32 dermatology* or chronicdisease or chronic condition or long term condition or chronic illness or incurable or
- 33 disability or life limiting or long term care or life threatning or palliative or assistive technology or continu* of
- 34 care or chronic car* or continuing car* or impact of chronic skin diseese).m_titl.
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- 36 40. "ichthyosis bullosa of Siemens"/ or X linked ichthyosis/ or ichthyosis/ or lamellar ichthyosis/ or
- 37 ichthyosis vulgaris/
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- 39 41. exp skin/ or exp skin disease/
- 40
- 41 42. psychological rating scale/ or Psychosocial Adjustment to Illness Scale/
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- 43 43. chronic disease/
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- 45 44. rare disease/
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- 47 45. diseases/co, dm [Complication, Disease Management]
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- 49 46. palliative nursing/
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- 51 47. eczema/
- 52 48. "Psoriasis Area and Severity Index"/ or psoriasis vulgaris/ or Psoriasis Severity Index/ or scalp
- 53 psoriasis/ or exp psoriasis/
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- 55 49. atopic dermatitis/ or exp dermatitis/
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- 57 50. 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49
- 58 51. (Child or children or infant* or toddler* or baby or babies or youngster* or young pers* or preschool* or
- 59 teenage* or adolescen* orprematu*).m_titl.
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14 58. 51 or 52 or 53 or 54 or 55 or 56 or 57
15 59. 15 and 28 and 38 and 50 and 58
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17 60. limit 59 to english language
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19 61. limit 60 to yr="2000 -Current"
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Search Strategy for MEDLINE

1	mental disorders/ or anxiety disorders/ or dissociative disorders/ or mood disorders/ or neurocognitive disorders/ or neurotic disorders/ or personality disorders/ or sexual dysfunctions, psychological/ or sleep wake disorders/ or substance-related disorders/ or "trauma and stressor related disorders"/
2	Psychiatry/nu, is [Nursing, Instrumentation]
3	exp fatigue/ or exp behavioral symptoms/
4	Stress, Psychological/co, di, ge, mo, nu, px [Complications, Diagnosis, Genetics, Mortality, Nursing, Psychology]
5	Depressive Disorder/nu, px [Nursing, Psychology]
6	Anxiety/ or Anxiety, Separation/ or Anxiety Disorders/ or Performance Anxiety/
7	Personal Satisfaction/
8	Social Stigma/ or Social Support/ or Social Behavior/ or Social Isolation/ or "Social Determinants of Health"/ or Social Perception/ or Psychology, Social/ or Social Marginalization/
9	Depression/nu, px [Nursing, Psychology]
10	Anxiety/ or Stress, Psychological/ or Adaptation, Psychological/ or Depression/
11	Stress, Psychological/nu, px [Nursing, Psychology]
12	Guilt/px [Psychology]
13	Embarrassment/ or Emotions/
14	Behavior, Animal/is [Instrumentation]
15	Cognition Disorders/ or Cognition/
16	Social Stigma/ or Social Values/ or Social Participation/ or Social Behavior Disorders/ or Social Support/ or Social Behavior/ or Social Isolation/ or Social Perception/ or Psychology, Social/ or Phobia, Social/ or Social Skills/ or Social Networking/ or Social Marginalization/
17	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18	limit 17 to abstracts
19	(Psychosocial or psycho-social or psychodermat* or social or cognit* or emotion* or well-being or psychologic* or adjust* disorder or depress* or anxiety or anxious or coping or stress or mental health or guilt or embarrassment).m_titl.
20	limit 19 to abstracts

21	18 or 20
22	(disease specific or dermatolog* specific or disease burden or burden of disease or scale or validat* or needs assessment or psychosocial assessment or index or tool or interview or quality of life or QoL or measure or impact or screen* or wellbeing or well being or questionnaire or health related quality of life or health profile or inventory or intervention or evaluation or schedule or survey or audit or neuropsychological assessment or activities of daily living or dermatolog* specific health instrument or psychosocial impact or psycho social impact).m_titl.
23	limit 22 to abstracts
24	"Quality of Life"/px [Psychology]
25	"Surveys and Questionnaires"/
26	"Health Services Needs and Demand"/ or Needs Assessment/
27	"Outcome Assessment (Health Care)"/ or Personality Assessment/ or Self-Assessment/ or Nursing Assessment/ or "Process Assessment (Health Care)"/ or Symptom Assessment/ or "Outcome and Process Assessment (Health Care)"/
28	"Severity of Illness Index"/
29	"Tool Use Behavior"/
30	"Quality of Life"/px [Psychology]
31	Interview, Psychological/ or Interview/
32	"Activities of Daily Living"/px [Psychology]
33	23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32
34	limit 33 to abstracts
35	23 or 34
36	(Caregiver* or family or 'family caregiver' or 'family care giver*' or parent or homecare* or home care* or adult or adults* or grownup* or grown up or families or relative or relation* or mother* or father* or family nurs* or primary care provider* or informal caregiver* or carer* or 'greater patient concept' or homecare).m_titl.
37	limit 36 to abstracts
38	Caregivers/px [Psychology]
39	Family/ or Family Health/ or Family Nursing/
40	Parents/px [Psychology]
41	Adult/px [Psychology]
42	Humans/px [Psychology]

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4	43	Siblings/px [Psychology]
5		
6	44	Grandparents/px [Psychology]
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8	45	38 or 39 or 40 or 41 or 42 or 43 or 44
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10	46	limit 45 to abstracts
11		
12	47	37 or 46
13		
14	48	(Ichthyos* or Skin* or skin condition* or skin disorder* or scaliness or keratos* or
15		cornificat* or rare skin dermatology* or chronic disease or chronic condition or long term
16		condition or chronic illness or incurable or disability or life limiting or long term care or
17		life threatening or palliative or assistive technology or continu* of care or chronic car* or
18		continuing car* or impact of chronic skin disease).m_titl.
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20		
21	49	limit 48 to abstracts
22		
23	50	Ichthyosis/ or Ichthyosis Vulgaris/ or Ichthyosis, X-Linked/ or Ichthyosis, Lamellar/ or
24		"Ichthyosis Bullosa of Siemens"/
25		
26	51	exp Skin/ or exp Skin Diseases/
27		
28	52	exp Dermatology/
29		
30	53	Psoriasis/ or Scalp Dermatoses/
31		
32	54	exp Dermatitis/ or exp Dermatitis, Atopic/
33		
34	55	Eczema/
35		
36	56	Chronic Disease/
37		
38	57	Rare Diseases/
39		
40	58	Palliative Care/ or Terminal Care/ or Chronic Disease/
41		
42	59	50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58
43		
44	60	limit 59 to abstracts
45		
46	61	49 or 60
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48	62	21 and 35 and 47 and 61
49		
50	63	limit 62 to (english language and yr="2000 -Current")
51		
52	64	exp Child/
53		
54	65	exp Infant/
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56	66	Child, Preschool/ or Infant/
57		
58	67	Adolescent/ or Young Adult/
59		
60	68	Infant, Premature, Diseases/ or Infant, Premature/ or Infant, Extremely Premature/ or Premature Birth/

69	64 or 65 or 66 or 67 or 68
70	limit 69 to abstracts
71	(Child or children or infant* or toddler* or baby or babies or youngster* or young pers* or preschool* or teenage* or adolescen* or prematur*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
72	limit 71 to abstracts
73	21 and 35 and 47 and 61 and 72
74	21 and 35 and 47 and 61
75	limit 74 to (english language and yr="2000 -Current")

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Search Strategy for PsychINFO

<input type="checkbox"/>	1	(Psychosocial or psycho-social or psychodermat* or social or cognit* or emotion* or well-being or psychologic* or adjust* disorder or depress* or anxiety or anxious or coping or stress or mental health or guilt or embarrassment).m_titl.
<input type="checkbox"/>	2	limit 1 to abstracts
<input type="checkbox"/>	3	Psychosocial Factors/ or Major Depression/
<input type="checkbox"/>	4	exp Psychosocial Assessment/
<input type="checkbox"/>	5	Mental Health/ or Well Being/ or Life Satisfaction/ or Anxiety/
<input type="checkbox"/>	6	Psychological Stress/ or Stress/ or Chronic Stress/ or Social Stress/
<input type="checkbox"/>	7	Guilt/
<input type="checkbox"/>	8	exp Embarrassment/
<input type="checkbox"/>	9	Social Identity/ or Social Isolation/ or Social Anxiety/ or Social Cognition/
<input type="checkbox"/>	10	3 or 4 or 5 or 6 or 7 or 8 or 9
<input type="checkbox"/>	11	limit 10 to abstracts
<input type="checkbox"/>	12	2 or 11
<input type="checkbox"/>	13	(disease specific or dermatolog* specific or disease burden or burden of disease or scale or needs assessment or psychosocial assessment or index or tool or interview or quality of life or validat* or QoL or measure or impact or screen* or wellbeing or well being or questionnaire or health related quality of life or health profile or inventory or intervention or evaluation or schedule or survey or audit or neuropsychological assessment or activities of daily living or dermatolog* specific health instrument or psychosocial impact or psycho social impact).m_titl.
<input type="checkbox"/>	14	limit 13 to abstracts

<input type="checkbox"/>	15	Test Reliability/ or Test Validity/ or "Quality of Life"/ or Measurement/ or Psychometrics/ or Questionnaires/
<input type="checkbox"/>	16	exp Caregiver Burden/
<input type="checkbox"/>	17	Questionnaires/
<input type="checkbox"/>	18	exp Rating Scales/ or exp Screening Tests/
<input type="checkbox"/>	19	Rating Scales/ or Screening Tests/
<input type="checkbox"/>	20	exp Needs Assessment/
<input type="checkbox"/>	21	measurement/ or needs assessment/ or "quality of life measures"/ or interviews/
<input type="checkbox"/>	22	"Activities of Daily Living"/
<input type="checkbox"/>	23	Surveys/
<input type="checkbox"/>	24	15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
<input type="checkbox"/>	25	limit 24 to abstracts
<input type="checkbox"/>	26	14 and 25
<input type="checkbox"/>	27	(Caregiver* or family or 'family caregiver' or 'family care giver*' or parent or homecare* or home care* or adult or adults* or grownup* or grown up or families or relative or relation* or mother* or father* or family nurs* or primary care provider* or informal caregiver* or carer* or 'greater patient concept' or homecare).m_titl.
<input type="checkbox"/>	28	exp Caregivers/
<input type="checkbox"/>	29	Family/ or Extended Family/ or Family Members/
<input type="checkbox"/>	30	Home Care/ or Home Care Personnel/
<input type="checkbox"/>	31	limit 27 to abstracts
<input type="checkbox"/>	32	28 or 29 or 30
<input type="checkbox"/>	33	limit 32 to abstracts
<input type="checkbox"/>	34	31 or 33
<input type="checkbox"/>	35	(Ichthyos* or Skin* or skin condition* or skin disorder* or scaliness or keratos* or cornificat* or rare skin dermatology* or chronic disease or chronic condition or long term condition or chronic illness or incurable or disability or life limiting or long term care or life threatening or palliative or assistive technology or

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		continu* of care or chronic car* or continuing car* or impact of chronic skin disease).m_titl.
<input type="checkbox"/>	36	limit 35 to abstracts
<input type="checkbox"/>	37	exp Skin Disorders/
<input type="checkbox"/>	38	Dermatitis/
<input type="checkbox"/>	39	Chronic Illness/ or Genetic Disorders/
<input type="checkbox"/>	40	Long Term Care/
<input type="checkbox"/>	41	Palliative Care/
<input type="checkbox"/>	42	37 or 38 or 39 or 40 or 41
<input type="checkbox"/>	43	36 or 42
<input type="checkbox"/>	44	12 and 26 and 34 and 43
<input type="checkbox"/>	45	limit 44 to (english language and yr="2000 -Current")

Search Strategy for CINAHL

#	Query	Limiters/Expanders
		Limiters - Published Date: 20000101-2021105; English Language Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S58	S14 AND S33 AND S44 AND S57	
S57	S52 OR S53 OR S54 OR S55 OR S56	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S56	(MH "Dermatology")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S55	(MH "Keratosi+s")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S54	(MH "Skin+s")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S53	(MH "Ichthyos+i+s") OR (MH "Ichthyosiform Erythroderma, Congenital+s")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S52	ichthyos* or skin* or scaliness or keratos* or cornificat* or dermatolog*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S51	S45 OR S46 OR S47 OR S48 OR S49 OR S50	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S50	(MH "Infant, Premature")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S49	(MH "Adolescence+s")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S48	(MH "Child, Preschool")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S47	(MH "Infant+s")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S46	(MH "Child+s")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S45	child* or infant* or toddler* or baby or babies or youngster* or "young pers*" or preschool* or teen* or adolescen* or prematur* or pediatric* or paediatric*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S44	S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S43	(MH "Primary Health Care")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S42	(MH "Family Nursing")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S41	(MH "Fathers+s")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S40	(MH "Mothers+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S39	(MH "Adult+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S38	(MH "Home Health Care+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S37	(MH "Parents+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S36	(MH "Family+") OR (MH "Extended Family+") OR (MH "Nuclear Family+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S35	(MH "Caregivers")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S34	caregiver* or family or "family caregiver" or "family care giver*" or parent or homecare* or "home care*" or adult or adults* or grownup* or "grown up" or families or relative* or relation* or mother* or father* or "family nurs*" or "primary care provider*" or "informal caregiver*" or carer* or "greater patient concept" or homecare	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S33	S15 OR S32	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S32	S31 N5 S30	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S31	("disease specific" or "dermatolog* specific" or "disease burden" or "burden of disease")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S30	S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S29	(MH "Activities of Daily Living+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S28	(MH "Audit")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S27	(MH "Surveys+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S26	(MH "Evaluation+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S25	(MH "Psychosocial Intervention")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S24	(MH "Inventories")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S23	(MH "Questionnaires+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S22	(MH "Psychological Well-Being")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S21	(MH "Health Screening+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S20	(MH "Interviews+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S19	(MH "Clinical Assessment Tools+") OR (MH "Research Instruments+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S18	(MH "Scales")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S17	(MH "Needs Assessment")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S16	(MH "Quality of Life+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S15	(“disease specific” or “dermatolog* specific” or “disease burden” or “burden of disease”) N5 (scale or “needs assessment” or “psychosocial assessment” or index or tool or interview or “quality of life” or validat* or QoL or measure or impact or screen* or wellbeing or “well being” or well-being or questionnaire or “health profile” or inventory or intervention or evaluation or schedule or survey or audit or “neuropsychological assessment” or “activit* of daily living” or “health instrument” or “psychosocial impact” or “psycho social impact”)	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S14	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S13	(MH "Embarrassment")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S12	(MH "Guilt+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S11	(MH "Mental Health")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S10	(MH "Coping+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S9	(MH "Anxiety+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S8	(MH "Depression+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S7	(MH "Adjustment Disorders+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

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S6	(MH "Adjustment Disorders+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S5	(MH "Stress, Psychological+") OR (MH "Diagnosis, Psychosocial+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S4	(MH "Psychological Well-Being")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S3	(MH "Emotions+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S2	(MH "Social Cognition") OR (MH "Cognition+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S1	psychosocial or psycho-social or psychodermat* or social or cognit* or emotion* or well-being or wellbeing or "well being" or psychologic* or "adjust* disorder" or depress* or anxiety or anxious or coping or stress or "mental health" or guilt or embarrassment	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

Search Strategy for Cochrane Central Register of Controlled Trials (CENTRAL)

‘Skin’ AND ‘caregiver’ AND ‘skin disease’ AND ‘dermatological tool’ were searched using the advanced search function.

Search Strategy for U Search

‘Caregiver’ AND ‘dermatology or skin disease’ AND ‘measurement tool or assessment tool’ AND ‘children or adolescents or youth or child or teenager’ were searched using the advanced search function.

Search Strategy for Web of Science

Query preview was ‘[ALL=(dermatology assessment tools)) AND ALL=(caregivers)]

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Supplementary file 3: Number of records identified during supplementary searches

Grey literature, bibliographies, online databases of QoL tools and several trial registers were searched on 01 April 2020 and updated on 05 Oct 2021.

Table 1: Records identified during original and updated supplementary searches

Tools included in search	Search category/term	Records (n) identified during original search (01 Jan 2000 to 01 April 2020)	Records (n) identified during updated search (01 April 2020 to 05 Oct 2021)	Number accessed in full text	Relevant (included in review)
Controlled Trials ISRCTN (www.controlled-trials.com/isrctn/)	'Skin and Connective Tissue Diseases'	241	2	3	0
United Kingdom (UK) Clinical Trials Gateway (www.ukctg.nihr.ac.uk/default.aspx)	'Skin and Cosmetic health'	72	2	0	0
United States(US) National Institutes of Health Ongoing Trials Register (www.clinicaltrials.gov)	'caregiver' and 'skin diseases'	24	0	1	0 (recruitment stage)
Australian New Zealand Clinical Trials Registry (www.anzctr.org.au)	'caregiver' and 'skin'	25	0	0	0
World Health Organization International Clinical Trials Registry platform (www.who.int/trialsearch)	'skin' and 'caregiver'	182	1	0	0
EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/)	'skin' and 'caregiver'	30	1	0	0
British Library Electronic Theses Online Service (EThOS) was searched using several combinations of key words	skin, instrument, caregiver, validation, psychosocial	0	2	2	0
OpenGrey database (www.opengrey.eu/) was searched (up to 22 November 2013)	'Skin Diseases'	89	1	0	0
Patient-Reported Outcome and Quality of Life Instruments Database (PROQOLID) (2002)		0	0	0	0
Handsearching of the bibliographies of included and excluded studies		48	3	0	0
Total		711	12	6	0

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Supplementary file 4: Methodological domains of the risk of bias criteria

Domains	Definitions	Grades and Criteria		
Validity Conceptual ¹ Construct ² Convergent ³	Does the tool measure what it is supposed to measure? Are the relevant domains captured? Does tool confirm hypothesized difference (eg diagnosis, clinical disease severity, others) Does the tool relate to other tools measuring the same construct?	A1: well balanced, objective and subjective domains B1: more focused on objective or subjective domains C1: missing important HRQOL domains	A2:>75% of results are in accordance with specific hypotheses B2: <75 of results are in accordance with specific hypotheses C2: no information	A3: correlation> B3: correlation < C3: no information
Interpretability Norms Categorization MCID ⁴	Are there standard comparative data from the general population and/or dermatology patients published and/or available? Are there categories of the obtained score available? Has the minimal change that is relevant to patients been reported?	A1: general and dermatology patients B1: general or dermatology patients C1: general nor dermatology patients	A2: using anchor or banding techniques B2: using distribution-based techniques C2: not reported	A3: MCID is known in heterogeneous sample B3: MCID is known in limited sample C3: not reported
Reliability ^{3,6} Internal consistency Retest-reliability	Does the tool provide a consistent answer? The extents to which items in a (sub) scale are intercorrelated, thus measuring the same construct (Cronbach's x)? Does a repeated administration of the tool within a reasonable period result in a similar outcome?	A1: 0.95>Cronbach's x>0.70 B1: Cronbach's x<0.7 or >0.95 C: Cronbach's x not reported	A2: x or ICC >0.7 B2: x or ICC <0.7 or correlation coefficients >0.7 C2: x or ICC not reported or correlation coefficient <0.7	
Structure	Have the domains and/or summary score of the tool been confirmed?	A: item response theory B: Factor analysis C: no factor analysis or item response theory		
Responsiveness	Is the tool sensitive to detect changes over time or due to therapy using patient centred and/or clinical criteria?	A: strong B: moderate or conflicting evidence C: absent, weak or solely based on statistical evidence		

Domains	Definitions	Grades and Criteria	
Item bias	Do the items of the tool function similar across external factors such as age, gender and diagnosis?	A: strong B: moderate or conflicting evidence C: absent or weak	
Cultural issues	Has the tool been translated using guidelines?	A1: always	A2: always
Translations	Has the tool been analysed in a cultural	B1: sometimes	B2: sometimes
Cultural equivalence	equivalence study?	C1: never, not reported	C2: never
Respondent burden	Is the length and content acceptable to the patients?	A: brief (<15min) B: long or problems of acceptability C: long and problems of acceptability	
Administrative burden	How easy is the tool to administer, score and interpret?	A: simple B: moderate C: complex	
Alternative forms	Is the tool available and tested for alternate forms of administration such as interviews in person or telephone, self-administration or computer-assisted interviews	A: strong evidence B: moderate or conflicting evidence C: absent or weak evidence	
Legend: ICC, intraclass correlation coefficient; ¹ Adjusted from Lohr et al (1996); Andresen (2000) and Terwee et al (2007); ² Objective and subjective domains are described by Muldoon et al (1998); ³ Criteria of construct validity and reliability were based on description by Terwee et al (2007); ⁴ MCID, minimal clinically important difference (ie the minimal difference, which is measured and is relevant to a patient and is not due to intrinsic variance of the instrument); ⁵ Refer to Table 2; ⁶ Reliability is concerned with the temporal stability of instrument scores (test-retest) and internal consistency, which is estimated by Cronbach's x, evaluates the relationship between all items (of a scale) and their ability to measure a single underlying domain. Test-retest reliability assess score consistency over two points in time assuming no change in health status and may provide a more rigorous of reliability due to the different sources of variance. Test-retest reliability should best be expressed in a x coefficient or ICC. Spearman's correlation coefficients are less optimal for retest reliability.			

Supplementary file 5: Figure 1:PRISMA Flow Chart for initial search (Jan 2000-April 2020)

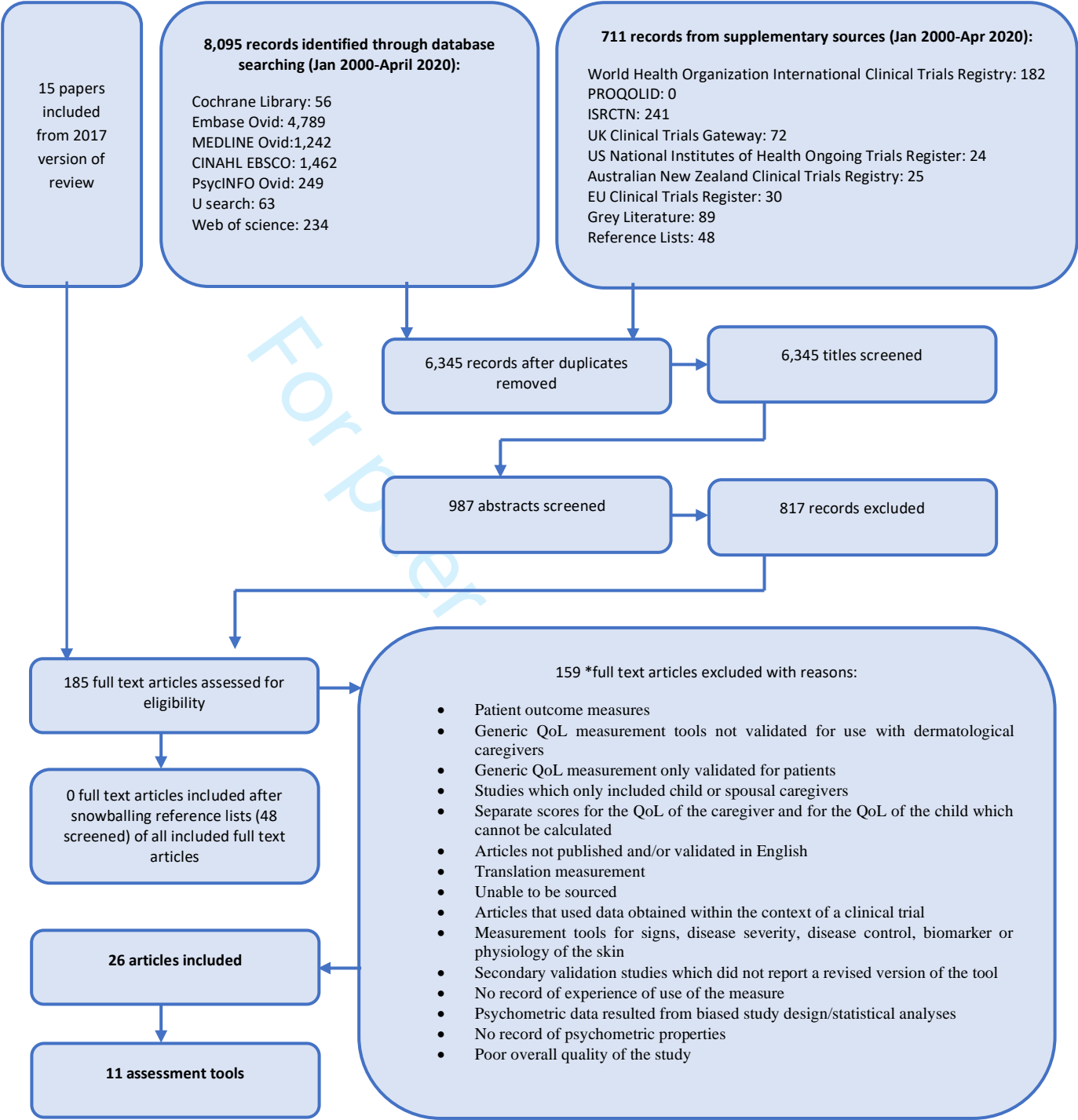


Figure 1 Legend:

PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.; CINAHL, Cumulated Index to Nursing and Allied Health Literature; EBSCO, Elton B. Stephens Company; PsycINFO, Psychological Information Database; U Search, Ulster University Search; PROQOLID, Patient-Reported Outcome and Quality of Life Instruments Database; ISRCTN, International Standard Randomised Controlled Trials Number; UK, United Kingdom; US, United States; EU, European Union; QoL, Quality of Life.

New studies included from updated search

During the updated search, a total of 173 records were identified. 161 records were identified from database searches and an additional 12 records were identified from supplementary searches. In total, 57 records were available after duplicates (n=114) were removed. 57 titles were screened. 5 abstracts were screened and 2 full text record were assessed for eligibility.^{1,2}

One record¹ identified no new measurement tool, with the **Family Dermatology Life Quality Index (FDLQI)** already included in our initial search. The second record² was excluded for a reason as listed in the exclusion criteria in Figure 1 (psychometric data resulted from biased study design). This exclusion was also justified by quotations from the paper ('Validity was established in a limited range of subjects', 'the parents that responded to the survey were all mothers', 'The present study was a single-institution cross-sectional study in Japan targeting parents of infants and toddlers (first-time patients less than 7 years old)').

In summary, no new studies and no new assessment tools were identified in our updated review. Please see PRISMA flow diagram (fig.2) below.

References

1. Zychowska M, Reich A, Maj J, Jankowska-Konsur A, Szepietowski J. Impact of Childhood Psoriasis on Caregivers' Quality of Life, Measured with Family Dermatology Life Quality Index. *J Eur Acad Dermatol Venereol* 2020; 100.
2. Sato H, Goto A, Murakami M, Kawabata Y. Development of a Pediatric Dermatology Screening tool based on Two Parent-Reported Skin Symptoms: Comparison of Parental Recognition and Physician Diagnosis of Skin Symptoms of Infants and Toddlers. *J Prim Care Community Health* 2020;11: 1-7.

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Figure 2: PRISMA Flow Diagram for updated search (01 Apr 2020 to 05 Oct 2021)

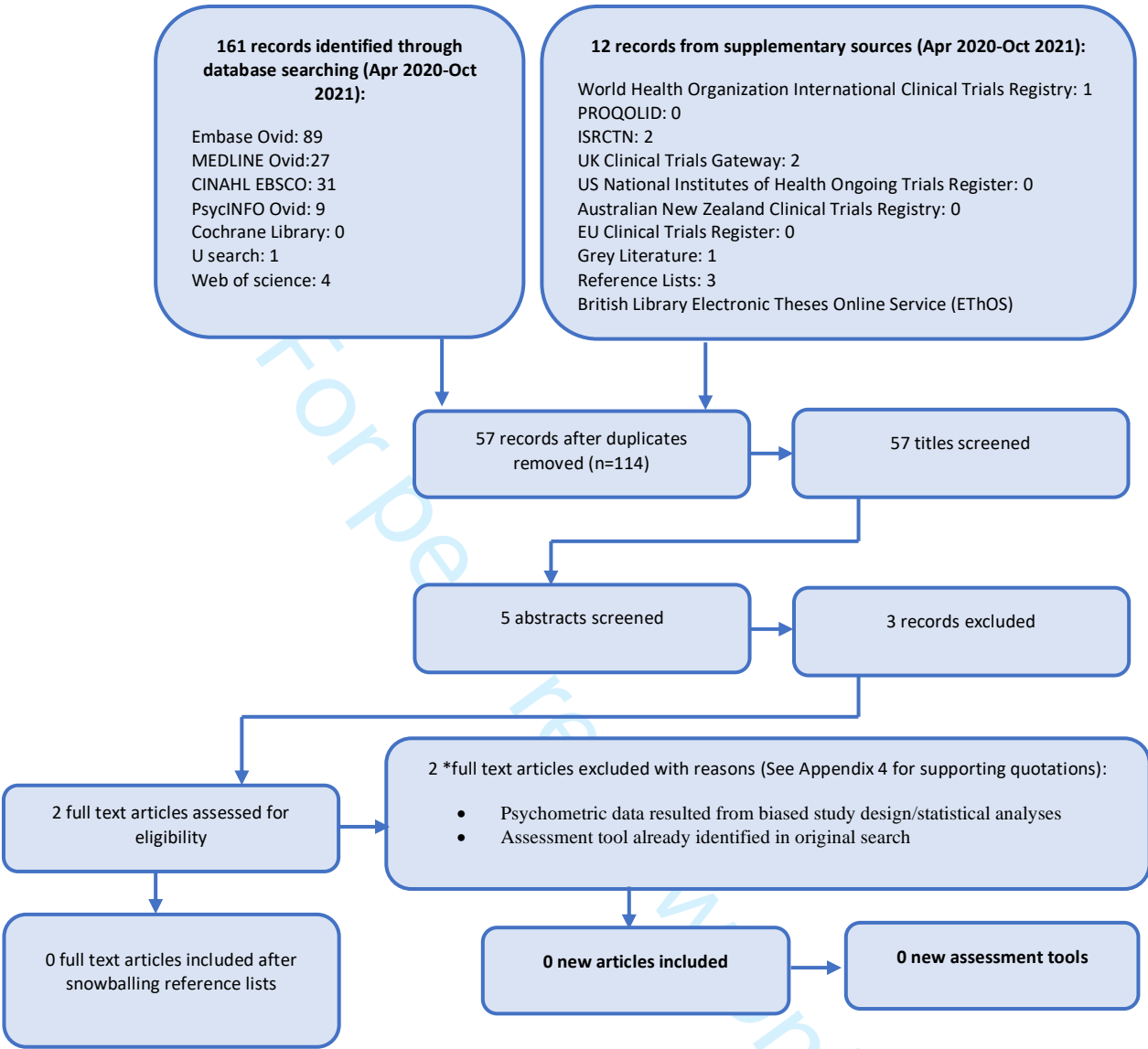


Figure 2 Legend:

PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.; CINAHL, Cumulated Index to Nursing and Allied Health Literature; EBSCO, Elton B. Stephens Company; PsycINFO, Psychological Information Database; U Search, Ulster University Search; PROQOLID, Patient-Reported Outcome and Quality of Life Instruments Database; ISRCTN, International Standard Randomised Controlled Trials Number; UK, United Kingdom; US, United States; EU, European Union.



PRISMA 2020 for Abstracts Checklist

Section and Topic	Item #	Checklist item	Reported (Yes/No)
TITLE			
Title	1	Identify the report as a systematic review.	yes
BACKGROUND			
Objectives	2	Provide an explicit statement of the main objective(s) or question(s) the review addresses.	Yes
METHODS			
Eligibility criteria	3	Specify the inclusion and exclusion criteria for the review.	Yes
Information sources	4	Specify the information sources (e.g. databases, registers) used to identify studies and the date when each was last searched.	Yes
Risk of bias	5	Specify the methods used to assess risk of bias in the included studies.	Yes
Synthesis of results	6	Specify the methods used to present and synthesise results.	Yes
RESULTS			
Included studies	7	Give the total number of included studies and participants and summarise relevant characteristics of studies.	Yes
Synthesis of results	8	Present results for main outcomes, preferably indicating the number of included studies and participants for each. If meta-analysis was done, report the summary estimate and confidence/credible interval. If comparing groups, indicate the direction of the effect (i.e. which group is favoured).	Yes
DISCUSSION			
Limitations of evidence	9	Provide a brief summary of the limitations of the evidence included in the review (e.g. study risk of bias, inconsistency and imprecision).	Yes
Interpretation	10	Provide a general interpretation of the results and important implications.	Yes
OTHER			
Funding	11	Specify the primary source of funding for the review.	Yes
Registration	12	Provide the register name and registration number.	Yes

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: <http://www.prisma-statement.org/>

BMJ Open

A systematic review of psychosocial needs assessment tools for caregivers of paediatric patients with dermatologic conditions.

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Primary Subject Heading:	Dermatology
Secondary Subject Heading:	Global health, Mental health, Medical education and training, Public health, Paediatrics
Keywords:	Paediatric dermatology < DERMATOLOGY, Dermatology < INTERNAL MEDICINE, MEDICAL EDUCATION & TRAINING, MENTAL HEALTH, PUBLIC HEALTH, PRIMARY CARE

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Title Page

A systematic review of psychosocial needs assessment tools for caregivers of paediatric patients with dermatologic conditions.

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A systematic review of psychosocial needs assessment tools for caregivers of paediatric patients with dermatologic conditions.

ABSTRACT

Objective: To identify validated dermatology-specific and disease-specific psychosocial needs assessment tools for caregivers of paediatric patients with dermatologic conditions. A secondary objective was to assess the adequacy of their measurement properties.

Design: Systematic review

Data Sources: EMBASE, PsycINFO, MEDLINE (in Ovid SP), Cochrane, CINAHL EBSCO, U Search and Web of Science were searched (2000 to 05 October 2021). Grey literature, bibliographies, online databases of QoL tools and several trial registers were searched (2000 to 05 Oct 2021).

Eligibility criteria: Eligible studies involved adult caregivers caring for a child (no age limit) with any form of any skin condition. Predetermined exclusion criteria, as per protocol, were applied to the search results.

Data abstraction and synthesis: Title, abstract, full-text screening, and data abstraction (standardised forms) were done independently in duplicate. Both's predefined methodological criteria assessed risk of bias. Narrative synthesis was used to present the findings.

Results: 187 full-text articles were examined from a total of 8979 records. Most tools were generic QoL tools, relevant to spouse/partner or based on their child's perception of the disease or assessed patients' quality of life. Following quality appraisal, 26 articles were identified, and 11 tools (one dermatology-specific and ten disease-specific) were included. Information outcome domains were provided for each tool (study-specific, questionnaire-specific, adequacy of measurement properties, risk of bias). No literature was found pertaining to the use of these tools within healthcare settings and/or as e-tools.

Discussion: With limited evidence supporting the quality of their methodological and measurement properties, this review will inform future dermatological COS development and improve evidence-based clinical decisions. Increasing demand on limited healthcare

resources justifies the co-development of an accessible solution-focused psychosocial needs assessment e-tool to promote caregiver health outcomes.

Funding: Bamford Centre for Mental Health and Wellbeing (Ulster University). Award/Grant number is not applicable.

Registration: PROSPERO (CRD42019159956). COMET Database.

For peer review only

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Strengths and limitations of this study

- The first systematic review to provide a comprehensive overview of psychosocial assessment tools validated for use among dermatological caregivers of paediatric patients.
- This study was conducted with the involvement of a health and life subject-specific librarian and an international multi-disciplinary expert group.
- The protocol was registered on the PROSPERO database (CRD42019159956), the COMET database and was conducted according to the recommendations from the PRISMA 2020 statement and ENTREQ statement.
- Adequacy of measurement properties was assessed using Both *et al*'s criteria
- Included articles were limited to being published in English between 2000-2021.

INTRODUCTION

Paediatric dermatology is a unique speciality in that children with lifelong and life-limiting skin disorders are increasingly being cared for by caregivers at home¹, which requires considerable cognitive, emotional, and physical resources.² Skin disease is the fourth leading cause of global disease burden with associated prevalence, care requirements and costs comparable with other diseases, such as cardiovascular disease and diabetes.³⁻⁵ Delayed identification of dermatological caregiver needs and provision of timely supports can seriously compromise the long-term psychosocial wellbeing of caregivers⁶⁻¹⁰ and particularly undermine the care and treatment of paediatric patients affected by rare or chronic skin disease.¹¹ Caregivers of skin disease require similar systems of monitoring and integrated biopsychosocial support as other comparable chronic conditions.

The World Health Organisation (WHO) directive,¹² recent international guidelines^{13,14} and reports^{9,15-16} emphasise the importance of identifying psychosocial needs assessment tools for use among long-term caregivers, particularly self-referral models. Timely and appropriate identification of caregivers' unmet psychosocial needs has the potential to reduce caregiver strain and increase their ability to provide quality care within the home at reduced public health cost. Although a psychosocial needs assessment could be considered preventative in nature, by anticipating caregiver burnout and decreasing the need for emergency interventions, there is a lack of evidence regarding the use of caregiver assessment tools within healthcare settings. To date, no comprehensive review of psychosocial needs assessment tools validated for use among informal dermatological caregivers of paediatric patients has been conducted. With increasing competition for valuable healthcare resources and services, there is an urgent need to reconceptualise global burden within the construct of 'prevention is better than cure' by informing evidence-based decisions and promoting caregiver health outcomes within day-to-day clinical practice.

Objectives: This review aimed to improve clinician access to existing dermatology-specific and disease-specific psychosocial needs assessment tools, validated for use among caregivers of paediatric patients with dermatologic conditions. Additionally, this review assessed the adequacy of their measurement properties.

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METHODS

This review was conducted according to the recommendations from the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement.¹⁷ The ENTREQ statement was read and guided in reporting the synthesis of the findings.¹⁸

Eligibility criteria

Studies which involved adult caregivers (age 18 years and over) caring for a child (no age limit) with any form of any skin condition were included. Predetermined exclusion criteria were adhered to (see protocol). Included articles were limited to being published in English between 01 January 2000 to 05 October 2021. This ensured that relevant assessment tools developed in the years before publication of the 2017 review¹⁹ were included as that review had limited their search to one database and quality-of-life measures only, which contrasts with the measures recommended by the Cochrane Skin Centre of Evidence Based Dermatology.

Information sources

MEDLINE, PsycINFO and EMBASE (OVID interface) and CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature) were searched (01 January 2000 to 05 October 2021). Grey literature, bibliographies, online databases of QoL tools and several trial registers were also searched (01 January 2000 to 05 October 2021). A ‘snowball’ search was carried out to identify additional studies by manually searching the reference lists of all publications eligible for full-text review. The PRISMA flow diagram (Fig. 1) includes the number of records identified from each source.

Search strategy

One known relevant systematic review¹⁹ was used as a starting point to identify records. A draft search strategy was developed by using candidate search terms that were identified in the titles, abstracts, and subject indexing of that systematic review. The full search strategy development process is included in Supplementary file 1. This strategy was tailored to the specifications of each of the databases searched and developed in collaboration with a subject-specific librarian (J.A.) and expert group. Each tailored database search strategy is

included in Supplementary file 2. All search terms/categories used to search within the supplementary sources are included in Supplementary file 3.

Selection and data collection process

Title, abstract and full-text screening were conducted manually in duplicate (independently) by two reviewers (C.W. and G.L.). Extracted data from full-text articles was processed using three standardised extraction forms: (i) Study-specific information included the name of the tool, country of origin, disease of affected patients, sample sizes used in each stage of its development and study setting (ii) Questionnaire-specific information included the outcome domains, number of items and subscales, recall period, scoring system, respondent feedback and administration mode and time (iii) Adequacy of measurement properties was evaluated using five methodological domains: validity, reliability, structure, interpretability, and transferability. At the full text screening stage, any discrepancies were resolved by discussion and, where necessary, the third author (M.Mc.L) was consulted.

Risk of bias assessment

Risk of bias in the included studies was assessed independently by two reviewers using Both *et al's*²⁰ criteria, made possible by the similarities between the studies. Each methodological domain and item were graded for risk of bias using predefined criteria. Any discrepancies were resolved by consensus discussions (C.W., G.L.) and, where necessary, by deferment to the third author (M.Mc.L). No overall risk of bias judgment that summarised across domains was given due to the wide variation in assessment across domains within each tool. To improve the robustness of the synthesis and facilitate replicability,²¹ an overview of the domain definitions, items, effect measures, grades and criteria used in assessing the risk of bias is provided in Supplementary file 4.

Synthesis methods

In line with synthesis guidelines,²² a narrative approach was used to arrange the results into two categories: dermatology- and disease-specific tools psychosocial needs assessment tools. To ease identification of variability between and within the included tools, results were also tabulated using the subheadings used in each of the three data extraction forms.

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Certainty assessment

The robust search strategy was validated in MEDLINE when it successfully identified the one known systematic review¹⁹ as part of the search strategy development process (Supplementary file 1). Two authors (C.W. and G.L.) independently assessed the certainty of evidence by assessing risk of bias using a predefined checklist of criteria.²⁰

Ethics Approval

Ethical approval for this review was obtained from University of Ulster Research Ethics Committee (Ref: REC/20/0004). Informed consent was obtained from all participating members of the expert group associated with the research project

Patient and Public Involvement (PPI)

An international multi-disciplinary expert group (n=15), including affected adults, clinical psychologists, consultant dermatologists, health policy advisors and caregivers, was established at the outset of the project (September 2017). Anonymity remains protected due to their ongoing involvement in another follow-on study. The Guidance for Reporting Involvement of Patients and the Public (GRIPP) Short Form checklist was used to improve the reporting of PPI in our study.²³ PPI helped identify the research question, guide in terms of review design (search strategy, inclusion and exclusion criteria and data extraction subheadings) and improve the dissemination of findings (invitations to poster and orally present at international dermatology and psychology conferences).

RESULTS

This review identified 8979 records: 8256 records from database searching and 723 records from supplementary sources. After duplicates were removed (n=2577), 6402 records were available. Of the 6402 titles screened, 992 abstracts were screened, and 187 full text articles were assessed for eligibility. This included 15 records identified from the one known systematic review. Of the 187 full text articles assessed for eligibility, 161 records were

excluded for reasons which met the exclusion criteria (PRISMA Flow Diagram Fig. 1). No full text records were included after snowballing reference lists (48 screened).

To improve transparency, summaries of the records identified during the initial and updated searches, for both databases and supplementary sources, are included in Supplementary files 3 and 5. PRISMA flow diagrams are included for both the initial search (01 Jan 2000 to 01 April 2020) [Supplementary file 5 (Fig.1)] and updated search periods (01 April 2020 to 05 October 2020) [Supplementary file 5 (Fig.2)] and provide a breakdown of the number of records identified for each database and supplementary source. The two full text articles, identified in the updated search, were both excluded when assessed for eligibility. One record²⁴ contained psychometric data resulting from a biased study design and statistical analysis ('validity was established in a limited range of subjects', 'the parents that responded to the survey were all mothers', 'single-institution cross-sectional study in Japan targeting parents of first-time patients less than 7 years old'). The other record²⁵ identified the Family Dermatology Life Quality Index (FDLQI), which was already identified in the initial search.

The majority of existing, validated dermatological assessment tools identified were generic quality of life (QoL) tools and/or assess the patients' quality of life. Of those tools validated for use among caregivers, most were either relevant to spouse/partner or depend on the caregiver to complete but are based on their child's perception of the disease (Fig. 1). Very few needs assessment tools were validated for use among caregivers of paediatric patients affected with dermatologic disease. In summary, a total of 11 assessment tools were identified from the 26 articles included in this review.²⁶⁻³⁶ Ten disease-specific assessment tools were identified (**PFI-15**²⁶, **Family Pso**²⁷, **QPCAD**²⁸, **CADIS**²⁹, **PIQoL-AD**³⁰, **DFI**³¹, **PASECI**³², **CarGOQoL**³³, **EB-BoD**³⁴ and **FBI**³⁵) and one dermatology-specific assessment tool was identified (**FDLQ**³⁶). Table 1 provides a summary of study-specific information and includes the name of tool, country of origin, disease of affected patient, sample sizes and study setting. Table 2 summarises questionnaire-specific information under the subheadings outcome domains, subscales, number of items, recall period, scoring system and administration time. Table 3 provides an overview of the adequacy of the measurement properties of the included tools, including transferability, reliability, validity, structural and

interpretability. Table 4 provides a graded risk of bias assessment (using the predefined criteria) of each methodological domain and item for each of the eleven tools.

Disease-specific needs assessment tools

The Family Psoriasis Index (PFI-15)²⁶ is recommended for use alongside a dermatology-specific tool. As it is assessed on current time only it does not rely on accurate recall. However, due to the small sample size, factor analysis could not be done and there is a lack of comparison of PFI scores with other generic family QoL scales. In order to achieve its Cronbach alpha value (0.86), it was necessary to delete five items. It has a weaker focus on the emotional aspects of living with affected members. Those accompanying patients to the primary care centre and inpatients were not included in the creation of the PFI, which restricts the generalisation of the quantitative findings.

The Family Pso²⁷ was created from interviews (n=95) with psoriasis patients and their family members. Three experts (no caregiver involvement) decided the generation items for piloting and item reduction. Other limitations include that a small sample was used in its testing and were predominantly female partners of the interviewees. Its advantages include that the wording is more focused on emotional aspects of caregiving as opposed to HR-QoL.

Four tools were found that assess the impact of atopic dermatitis on the family. The **Quality of life in Primary Caregivers of Children with Atopic Dermatitis (QPCAD)**²⁸ has a one week recall and has been validated for use among primary caregivers of children with AD in the Japanese version only. Convergent validity requires further study and only caregivers of mild and moderate patients from an urban area were included in the study.

The **Childhood Atopic Dermatitis Impact Scale (CADIS)**²⁹ is validated for use with both patients and parents of patients younger than six years. Rasch analysis reduced the tool to a 45-item version which is responsive to clinical change in AD.

The **Parents' Index of Quality of Life in Atopic Dermatitis (PIQoL-AD)**³⁰ assesses the impact of AD on caregivers of affected children, aged eight years or younger. The PIQoL-AD adopts a dichotomous response system which is less sensitive to subtle changes in HR-QoL and includes only items that consider the negative aspects of psychological well-being.

The **Dermatitis Family Impact (DFI)**³¹ tool is the tool most widely reported in studies, having been used in over 750 clinical trials, although often at longer intervals despite being validated for use with a one-week recall period. As most of DFI studies are in secondary care hospitals, there exists the possibility of maximising the chances of the DFI scores showing significant improvements following an intervention.³¹ Dodington's review³⁷ found that internal consistency and test-retest reliability was adequately demonstrated, but highlighted that psychometric measures were less well established due to a lack of vigour in both the creation and validation processes. No valid score-banding descriptors of DFI score meanings are included and no information to establish the MCID of DFI score is available.³¹ No studies demonstrated dimensionality, factor structure or differential item functioning.

The final tool included in this review was the **Parental Self-Efficacy with Eczema Care Index (PASECI)**³². It is a generalised self-efficacy scale focusing on the management of four subscales: medication, symptoms, personal challenges, and communication with healthcare teams. It has a two-factor structure which considers the performance of routine management tasks and the management of child symptoms and behaviour. There was reliance on self-reported data, potentially affecting the fidelity of the results. More research is needed on banding and categorisation.

Validation of **The CareGiver Oncology Quality of Life (CarGOQoL)**³³ was carried out using dermatology experts other than caregivers. Several non-optimal indicators of validity are indicated in Table 4.

The **Epidermolysis Bullosa – Burden of Disease (EB-BoD)**³⁴ tool needed to remove non-discriminatory items, such as frustration and guilt, from the original FBI³⁸ during its creation. It requires further validation in larger EB patient and/or caregiver groups before being revalidated for use in other languages and cultures.

The Family Burden of Ichthyosis (FBI)³⁵ is the only validated disease-specific questionnaire which measures the concept of burden for ichthyosis caregivers. The monocentric study used parents and their affected children in the creation of verbatim using an unnamed French social assessment, which could not be accessed for this review. Selection bias was a possibility as 40% of participants cared for those affected by severe forms of ichthyosis

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(severity score 50 or greater). Limitations include that validation of the FBI was carried out using parents of children affected with only the severest forms of ichthyosis. Although itch is one of the significant challenges named by parents of children affected with ichthyosis (third most significant impact during the validation of the DFI³¹), it does not feature as an item. Similarly, no items relate to pain in the finalised FBI.³⁵ Verification of its psychometric properties, preferably in a multicentre study is required. Caregiver feedback included that the finalised generation items were negatively phrased. The original French questionnaire has been linguistically and culturally adopted in Italy.³⁸

Dermatology-specific needs assessment tools

The **Family Dermatology Life Quality Index (FDLQI)**³⁶ is the most used dermatology-specific HR-QoL. The psychosocial impact loaded six items (emotional impact, physical wellbeing, impact on relationships, leisure, social life, and people’s reactions) and the physical impact loaded four items (burden, effect on job/study, household expenditure and housework). Fifty semi-structured interviews took place which informed the items generated for testing during piloting. The feedback (n=59 items) from these interviews has been termed ‘the greater concept’. Piloting of the 19 items occurred with 20 parents or partners of those originally interviewed, potentially introducing bias. Limitations include that the life-course of skin disease is not reflected in the FDLQI and that it depends on recall accuracy. Definitions, such as MID and the meaning of FDLQI scores are missing and future research is required to show the unidimensionality of the tool. The FDLQI was not tested for responsiveness for clinical change in a hospital or intervention context. Several items cannot discriminate between inflammatory and uninflammatory groups.

One common theme which emerged was the variation in methodological rigor used in measuring informal dermatological caregiver needs. Using the risk of bias assessment, each of the reviewed tools indicated an incomplete psychometric overview meaning that the generalisability and interpretation of results remain limited. Each reviewed tool (11 of 11; 100%) evaluated four or more psychometric properties. They do not comply with the

OMERACT filter criteria and consequently are unable to be included in the development of a future COS.³⁹

In terms of structure, five tools reported the use of factor analysis.^{27,32-34,36} Three tools reported the use of the more recently developed item response theory (IRT) to determine psychometric properties.^{26,29,30} Other tools neither reported factor analysis or IRT.^{28,31,35} Apart from two tools reporting strong item bias,^{26,30} the other nine tools^{27-29,31,32-35,36} reported weak item bias. One tool³¹ reported the use of distribution-based categorisation techniques, but the other ten tools did not report on categorisation. MCID was not reported for any tool other than one.³⁰

In terms of reliability, all tools reported a high internal consistency ($IC > 0.95$). Two tools did not report their retest reliability.^{27,35} One reported a weak retest reliability³³ ($ICC < 0.70$), while the other eight tools reported a good retest reliability^{26,28-32,34,36} ($ICC > 0.70$). In terms of conceptual validity, four tools have less well-balanced domains.^{28-30,33} The other seven tools include well balanced domains.^{26,27,31,32,34-36} No information is given regarding the construct validity for one tool.²⁷ Five tools demonstrate that $< 75\%$ of results are in accordance with their hypothesis^{31,32-35} and five tools demonstrate that $> 75\%$ of results are in accordance with their hypothesis.^{26,28-30,35} The majority of tools demonstrate poor convergent validity apart from two^{31,32} (> 0.70). The PFI-15 provides no information on convergent validity.³⁶ The other eight tools in this review show a convergent validity value of < 0.70 .^{27-30,33-36}

Table 1: Study-specific Information relevant to included assessment tools

References of included publications (first author, year, reference)	Country of Origin	Disease of affected patients	Name of Measurement Instrument	Sample size (n)	Study setting
Eghlileb et al ²⁶ (2009)	United Kingdom (UK)	Psoriasis	Psoriasis Family Index (PFI-15)	Interviews (Unknown)	Monocentric Outpatient clinic
Mrowietz et al ²⁷ (2017)	Germany	Psoriasis	Family Pso QoL in Primary Caregivers of children with Atopic Dermatitis (QPCAD)	Interviews (14) Piloting (96) Validation (96)	Monocentric Outpatient clinic
Kondo-Endo et al ²⁸ (2009)	Japan	Atopic Dermatitis	Childhood Atopic Dermatitis Impact Scale (CADIS)	Interviews (unknown) Pilot (33) Validation (400)	Monocentric Outpatient clinic
Chamlin et al ²⁹ (2005)	United States of America (USA)	Atopic Dermatitis	Parent's Index QoL - Atopic Dermatitis (PIQoL-AD)	Interviews (unknown) Piloting (20) Validation (300)	Two dermatology paediatric practices (San Francisco & Chicago)
McKenna et al ³⁰ (2005)	UK, Netherlands, Italy, Spain, USA, Switzerland, Germany, France (simultaneous development)	Atopic Dermatitis	Dermatitis Family Impact (DFI)	Interviews (65) Piloting (140 total) Validation (ranged between countries 45-328)	Monocentric Outpatient clinic
Lawson et al ³¹ (1998)	UK	Dermatitis		Interviews (29) & Focus Groups (10) Piloting (14) Validation (56)	Monocentric Outpatient clinic

Continued

References of included publications (first author, year, reference)	Country of Origin	Disease of affected patients	Name of Measurement Instrument	Sample size (n)	Study setting
Ersser et al ³² (2015)	UK	Eczema	Parental Self-Efficacy with Eczema Care Index (PASECI)	Literature review-generation items Piloting & Validation (242)	Monocentric Outpatient clinic
Minaya et al ³³ (2012)	France	Skin cancer	CareGiver Oncology Quality of Life (CarGOQoL)	Interviews (77) Piloting (837) Validation (unknown)	Monocentric Outpatient clinic
Dufresne et al ³⁴ (2015)	France	Epidermolysis Bullosa	Epidermolysis Bullosa - Burden of Disease (EB-BOD)	Complaints (23) informed item generation Piloting (Lionbridge institution) Validation (55)	Monocentric Outpatient clinic
Dufresne et al ³⁵ (2013)	France	Ichthyosis	Family Burden Ichthyosis (FBI)	Interviews (94) Piloting (42) Validation (30)	Monocentric Outpatient clinic
Basra et al ³⁶ (2008)	UK	All - general dermatology instrument	Family Dermatology Life Quality Index (FDLQI)	Interviews (50) Piloting (20) Validation (14)	Monocentric Outpatient clinic

Table 2: Questionnaire-specific information relevant to included assessment tools

Name of Measurement Instrument	Outcome domains measured	Number of items and subscales	Recall Period	Scoring system	Respondent Feedback	Admin Mode (Time in minutes)
Psoriasis Family Index (PFI-15) ²⁶	Social Life, Leisure activities Sporting activities, People's reactions, Worry about future Housework, Relationships Treatment duration, Clothing Shopping, Sleep	15 items	Now	4-point scale (0-3)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (2)
Family Pso ²⁷	Emotional Domain-emotional impact. Social Domain -Impact on daily activities & work /school and treatment. Leisure Domain - Influence on leisure/ personal relationships	15 items	1 month	5-point Likert format (0-4) and 'Does not apply'	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (3)
QoL in Primary Caregivers of children with Atopic Dermatitis (QPCAD) ²⁸	Achievement (3) Worry (6) Family co-operation (3) Exhaustion (8)	19 items	Past week	5-point scale (none to extremely)	Brief in length Moderate to administer, score and interpret Conflicting evidence of alternative forms	Self-report (unknown)
Childhood Atopic Dermatitis Impact Scale (CADIS) ²⁹	Impact on family (3 domains) Sleep and emotions Family & social function	45 items	1 month	5-point scale (never to all the time)	Long in length and problems of acceptability Moderate to administer, score and interpret Absent evidence of alternative forms	Self-administered (6)

Continued

Name of Measurement Instrument	Outcome domains measured	Number of items and subscales	Recall Period	Scoring system	Respondent Feedback	Admin Mode (Time in minutes)
Parent's Index QoL - Atopic Dermatitis (PIQoL-AD) ³⁰	1 domain - needs that can be influenced by a child with a diagnosis of AD	28 items	Not reported	5-point scale (never to all the time)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (3)
Dermatitis Family Impact (DFI) ³¹	Personal relationships and helping with treatment, Food and feeding, Sleep, Housework Shopping, Financial, Leisure Tiredness, Emotional distress	10 items	1 week	4-point scale (not at all, a little, a lot, very much)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (unknown)
Parental Self-Efficacy with Eczema Care Index (PASECI) ³²	Managing medications Managing eczema & symptoms Communication with Healthcare teams Managing Personal challenges	29 items 4 subscales	1-week pre and 4 weeks post intervention	11-point Likert Scale	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Clinician administered (3)
CareGiver Oncology Quality of Life questionnaire (CarGOQoL) ³³	Psychological well-being, Burden, Relationship with health care, Administration and finances, Coping, Physical well-being, Self-esteem, Leisure time Social support and private life	29 items	1 week	5-point Likert scale (never/not at all, rarely/a little, sometimes/somewhat, often/a lot, always/very much)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (3)
Epidermolysis Bullosa - Burden of Disease (EB-BOD) ³⁴	Economic and Social impact (5) Family Life (7) Disease & Treatment (5) Child's Life (3)	20 items	Not stated	7- point scale (always, very often, often, sometimes, rarely, never, not applicable)	Moderate to administer, score and interpret Absent evidence of alternative forms Long in length and problems of acceptability	Self-administered (unknown) Continued

Name of Measurement Instrument	Outcome domains measured	Number of items and subscales	Recall Period	Scoring system	Respondent Feedback	Admin (Time in minutes)	Mode in
Family Burden Ichthyosis (FBI) ³⁵	Work & Psychological impact, Daily Life, Pain, Familial and Personal Relationships	25 items	Not stated	4-point scale (definitely yes, maybe, definitely not, I don't know)	Long in length and problems of acceptability Moderate to administer, score and interpret	Self-administered (3)	
Family Dermatology Life Quality Index (FDLQI) ³⁶	Housework & expenditure Emotional & Physical wellbeing Impact on study/job, Social Life Burden of care, Leisure Activities	10 items	1 month	4-point scale (not at all/not applicable, a little, quite a lot, very much)	Brief in length Simple to administer, score and interpret Weak evidence of alternative forms	Self-administered (3)	

Table 3: Adequacy of the measurement properties relevant to included assessment tools with excellent and good methodological quality

Name of Measurement Instrument	Transferability	Reliability	Validity	Structure	Interpretability
Psoriasis Family Index (PFI-15) ²⁶	Sometimes translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - well balanced domains Construct >75% results in accordance with hypothesis Convergent - No information	IRT Weak sensitivity to detect changes Strong item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
Family Pso ²⁷	Never translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC not reported or correlation coefficient <0.70	Conceptual - more focused on objective/subjective domains Construct - no information Convergent <0.70	Factor analysis Weak sensitivity to detect changes Weak item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
QoL in Primary Caregivers of children with Atopic Dermatitis (QPCAD) ²⁸	Never translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - more focused on objective/subjective domains Construct <75% results in accordance with hypothesis Convergent <0.70	Satisfactory response to change in disease severity Satisfactory test-retest reliability	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
Childhood Atopic Dermatitis Impact Scale (CADIS) ²⁹	Sometimes translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - well balanced domains Construct >75% results in accordance with hypothesis Convergent <0.70	IRT Strong sensitivity to detect changes Weak item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - not reported
Parent's Index QoL - Atopic Dermatitis (PIQoL-AD) ³⁰	Always translated using guidelines Never analysed in a cultural equivalence study	IC: 0.95 > Cronbach's α >0.70 Retest reliability: k or ICC >0.70	Conceptual - more focused on objective/subjective domains Construct >75% results in accordance with hypothesis Convergent <0.70	IRT Strong sensitivity to detect changes item bias Strong item bias	Norms - General nor dermatology patients Categorisation - not reported MCID - known in heterogeneous sample

						Norms - General nor dermatology patients
		Always translated using guidelines	IC: 0.95 > Cronbach's α >0.70	Conceptual - well balanced Construct <75% results in accordance with hypothesis Convergent >0.70	No factor analysis or IRT Strong sensitivity to detect changes Weak item bias	Categorisation - used distribution-based techniques MCID - not reported
Dermatitis Family Impact (DFI) ³¹	Sometimes analysed in a cultural equivalence study		Retest reliability: k or ICC >0.70			
Parental Self-Efficacy with Eczema Care Index (PASECI) ³²	Always translated using guidelines	IC: 0.95 > Cronbach's α >0.70	Conceptual - well balanced Construct <75% results in accordance with hypothesis Convergent >0.70	Factor analysis Satisfactory response to change in disease severity Weak item bias		Norms - General nor dermatology patients
	Never analysed in a cultural equivalence study	Retest reliability: k or ICC >0.70				Categorisation - not reported MCID - not reported
CareGiver Oncology Quality of Life Questionnaire (CarGOQoL) ³³	Sometimes translated using guidelines	IC: 0.95 > Cronbach's α >0.70	Conceptual - more focused on objective/subjective domains Construct <75% results in accordance with hypothesis Convergent <0.70	Factor analysis Low / moderate sensitivity to changes Weak item bias		Norms - General nor dermatology patients
	Never analysed in a cultural equivalence study	Retest reliability: k or ICC <0.70				Categorisation - used distribution- based techniques MCID - not reported
Epidermolysis Bullosa - Burden of Disease (EB-BOD) ³⁴	Sometimes translated using guidelines	IC: 0.95 > Cronbach's α >0.70	Conceptual - well balanced Construct <75% results in accordance with hypothesis Convergent <0.70	Factor analysis Weak sensitivity to detect changes Weak item bias		Norms - General nor dermatology patients
	Never analysed in a cultural equivalence study	Retest reliability: k or ICC >0.70				Categorisation - not reported MCID - not reported
		IC: 0.95 > Cronbach's α >0.70				
Family Burden Ichthyosis (FBI) ³⁵	Sometimes translated using guidelines	Retest reliability: k or ICC not reported or correlation coefficient <0.70	Conceptual - well balanced Construct <75% results in accordance with hypothesis Convergent <0.70	No factor analysis or IRT Weak sensitivity to detect changes Weak item bias		Norms - General nor dermatology patients
	Never analysed in a cultural equivalence study					Categorisation - not reported MCID - not reported
Family Dermatology Life Quality Index (FDLQI) ³⁶	Always translated using guidelines	IC: 0.95 > Cronbach's α >0.70	Conceptual - well balanced domains Construct >75% results in accordance with hypothesis Convergent <0.70	Factor analysis Strong sensitivity to detect changes Weak item bias		Norms - General nor dermatology patients
	Never analysed in a cultural equivalence study	Retest reliability: k or ICC >0.70				Categorisation - not reported MCID - not reported

Legend: IRT, item response theory; IC, internal consistency; ICC, intraclass correlation coefficient; MCID, minimal clinically important difference.

Table 4. Evaluation of disease-specific and dermatology-specific tools (Risk of bias assessment criteria outlined in Supplementary file 4)

Criteria	PFI-15 ²⁶	Family Pso ²⁷	QPCAD ²⁸	CADIS ²⁹	PiQoL-AD ³⁰	DFI ³¹	PASECI ³²	CarGOQoL ³³	EB-BoD ³⁴	FBI ³⁵	FDLQI ³⁶
Validity											
Conceptual	A	B	B	A	B	A	A	B	A	A	A
Construct	A	C	B	A	A	B	B	B	B	B	A
Convergent	B	B	B	B	B	A	A	B	B	B	B
Interpretability											
Norms	C	C	C	C	C	C	C	C	C	C	C
Categorization	C	C	C	C	C	B	C	B	C	C	C
MCID	C	C	C	C	A	C	C	C	C	C	C
Reliability											
Internal consistency	A	A	B	A	A	A	A	A	A	A	A
Retest reliability	A	C	A	A	A	A	A	C	A	C	A ¹
Structure	A	B	B	A	A	C	B	C	B	C	B
Responsiveness	C	C	B	A	A	A	B	C	C	A	A
Item bias	A	C	C	C	A	C	C	C	C	C	C
Cultural issues											
Translations	B	C	C	B	A	A	A	B	B	B	A
Cultural equivalence	C	C	C	C	C	B	C	C	C	C	C
Respondent burden	A	A	A	B	A	A	B	B	B	B	A
Administrative burden	A	A	B	B	A	A	B	B	B	B	A
Alternative forms	C	C	B	C	C	C	C	C	C	C	C

Legend: PFI-15, The Family Psoriasis Index; Family Pso, Family Psoriasis; QPCAD, QoL in primary caregivers of children with atopic dermatitis; CADIS, Childhood Atopic Dermatitis Impact Scale; PiQoL-AD, Parents' Index QoL Atopic Dermatitis; DFI, Dermatitis Family Index; PASECI, Parental Self-Efficacy with Eczema Care Index; CarGOQoL, The CareGiver Oncology Quality of Life; EB-BoD, Epidermolysis Bullosa Burden of Disease; FBI, Family Burden Ichthyosis; FDLQI, Family Dermatology Life Quality Index; MCID, minimal clinically important difference; ¹ Objective and subjective domains are described by Muldoon et al (1998).

DISCUSSION

This is the first systematic review to address gaps in the existing evidence base around the identification of appropriate psychosocial needs assessment for caregivers of paediatric patients with dermatologic conditions. This topic represents an emerging area for which there is a lack of up-to-date good quality synthesised evidence. With increasing numbers of paediatric patients of chronic skin disease being cared for by informal caregivers, often with limited medical training, key international multi-disciplinary stakeholders (including clinicians, dermatological caregivers, and policymakers) emphasised an urgent need to improve clinician awareness of existing needs assessment tools, to help them make informed evidence-based decisions relating to assessment. The need to promote caregiver health outcomes within day-to-day clinical practice has become even more significant during Covid-19, a period of enhanced social isolation and increased caregiver hypervigilance and burnout.

This review identified eleven psychosocial needs assessment tools validated for use among caregivers of paediatric patients with dermatologic conditions. A narrative approach was used to arrange the reviewed tools into two groups: dermatology-specific and disease-specific tools. To ease identification of risk of bias, study variability and measurement properties between and within the included tools, results were additionally tabulated using the predefined subheadings on the data extraction forms.

Although skin disease may be characterised at times by unpredictable episodes in symptom severity,^{33,34,36} that requires similar systems of monitoring and integrated biopsychosocial support as other chronic conditions,^{5,40} our review highlights the lack of literature pertaining to the use of these assessment tools in healthcare settings. This review suggests that the mismatch between the recognised impact of caregiving for skin disease and the failure of practitioners to effectively engage with its management may be attributed to the biomedical model of assessment reflected in existing tools.

In contrast to the tools reviewed,²⁶⁻³⁶ which utilised measures of other constructs as a proxy for caregivers' need, it appears vital to directly assess informal dermatological caregivers' needs (at problem area and support level) and plan for how that knowledge will be used to

help support these needs.⁴¹⁻⁴³ Similarly, future assessments should use the scope of the International Classification of Functioning, disability, and health (ICF)⁴⁴ to inform their caregiver framework in terms of contextual factors and in terms of functioning and disability. Despite the recognised difficulty of assessing chronic pathologies by clinical or quality of life (QoL) aspects alone,^{45,46} most tools identified in this review were generic QoL tools. The European Academy of Dermatology and Venereology (EADV) Quality of life task force,⁴⁷ Cochrane Skin Centre of Evidence Based Dermatology⁴⁸ and the Harmonising Outcome Measures for Eczema (HOME) initiative³⁹ reinforce that generic QoL assessments do not encompass the many factors that contribute to the psychosocial burden of skin disease⁴⁹ and are not as sensitive, responsive, or relevant to individual patients or their caregivers.⁵⁰

We considered appropriate measurement tools to be theoretically driven, rigorously conceptualised with input from caregivers at each stage, consider disease life-course, tested for validity and reliability and intended to assess caregiver needs in relevant settings.^{39,41,47,48} Conceptual and theoretical work on dermatological caregivers' needs could have been relatively lacking because of the varying degree by which the tools were informed by caregiver experience, with minimal description of the questionnaire development process, absence of or exclusionary key definitions such as family, caregiver and domain and participants were not asked to clarify their relationship to the patient attending the outpatient clinics. Some of the tools only included items for the negative aspect of psychological wellbeing.^{31,35,36}

Healthcare teams require access to validated assessment tools which consider all dimensions along the care continuum and which do not use measures of other constructs as a proxy for caregivers' needs⁵¹ to provide culturally sensitive care. An international multicentric approach could best address variables including culture, demographics and disease severity. Although none of the reviewed assessment tools allow for the assessment of disease variables, including disease severity, we recommend that future needs assessment tools include disease parameters when designing their assessment framework. Dufresne³⁵ found that increased disease severity led to increased caregiver burden,

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suggesting that tools which assess factors relevant to clinical severity of disease could better inform the types of supports needed long-term.

Future assessment should be practical and feasible for daily use within busy clinics. A self-reporting psychosocial needs assessment e-tool, developed to identify caregiver needs (at both problem and support level), could best serve to address non-clinical barriers to assessment, including lack of time, support staff and easy tools, to reduce the reported high rates of non-use of validated tools within daily practice.⁵² Research reinforces improved care recipient and caregiver outcomes⁴¹⁻⁴⁴ when caregivers are facilitated to regularly self-report perceived needs enabling clinicians to identify and/or triage unmet psychosocial care needs.

Strengths and Limitations:

Strengths include a published protocol, a multi-disciplinary expert group and health science librarian involved in the design of the review, a comprehensive literature search, information provision on study, questionnaire, measurement properties and risk of bias. This review also provides key recommendations for future research. Although time was needed to ensure that members were involved as equal partners in debates and decisions around key issues, benefits of PPI included having experts with lived experience who creatively contributed towards the methodology. Limitations included studies published in the English language between 2000-2021.

To enhance the chances of developing a truer set of outcome domains for improved Core Outcome Set (COS) uptake, future assessments should adopt a more thorough typology to assess the degree to which deficits in caregivers' needs are present and to develop transparent conceptual frameworks which include key definitions and which are built upon a hybrid model using good quality caregiver frameworks alongside qualitative feedback from large and culturally diverse international cohorts of caregivers.⁵³ With increased emphasis on e-healthcare, it seems both desirable and practical to conceptualise an accessible and solution-based model of future e-assessment which can address recognised healthcare challenges, including limited clinic time, poor caregiver identification and healthcare communication,⁵³⁻⁵⁸ allowing for timely identification and/or triage of unmet

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3 psychosocial needs by practitioners while strengthening a caregiver's sense of autonomy,
4 coping ability and resilience.^{59,60} To inform the development of solution-focused
5 assessment e-tools, it is important that research is also conducted into which supports are
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7 rated as most important by informal dermatological caregivers.
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10 11 **CONCLUSION** 12

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14 Although no gold-standard tool exists for measuring the psychosocial needs of
15 dermatological caregivers, this comprehensive review improves clinician awareness and
16 knowledge of eleven validated psychosocial needs assessment tools for caregivers of
17 paediatric patients with dermatologic conditions. It is hoped that this review will inform the
18 development of solution-based models of outcome assessment for improved dermatology
19 care coordination. As dermatological caregiving research moves forward with significant
20 public and private investment, rigorous measurement of caregivers' needs is essential for
21 the development of social services, public policies and improved COS uptake. These findings
22 have implications for clinical practice, service development and future research, and
23 reinforce that attitude towards caregivers is pivotal in developing assessment for the
24 purpose of accessing supports and services.
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Competing interests Abstract was selected for paper presentation by the European Society for Dermatology & Psychiatry Conference in June 2021. Abstract has also been selected for publication by the British Journal of Dermatology.

Data Sharing statement All data relevant to the study are included in the article or uploaded as a supplementary information file.

Amendments to protocol Revisions to PROSPERO protocol reflect (i) the later initial search start date (to allow for preliminary searches to tailor the comprehensive search strategies) (ii) 19-year search period limit changed to a 21-year search period limit in the inclusion criteria to reflect updated search request (iii) inclusion of Both *et al*'s adequacy of measurement criteria (iv) exclusion criteria updated to include 'assessment tool already identified in initial search'.

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4 patient self-Reporting of Adverse-events: Patient Informationn and aDvice: a pilot
5 study protocol in pelvic radiotherapy. *Pilot Feasibility Stud* 2018;4:1-15.
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10 Activities and Emotional States of Informal Caregivers. *Proceedings* 2018;2:1-11.
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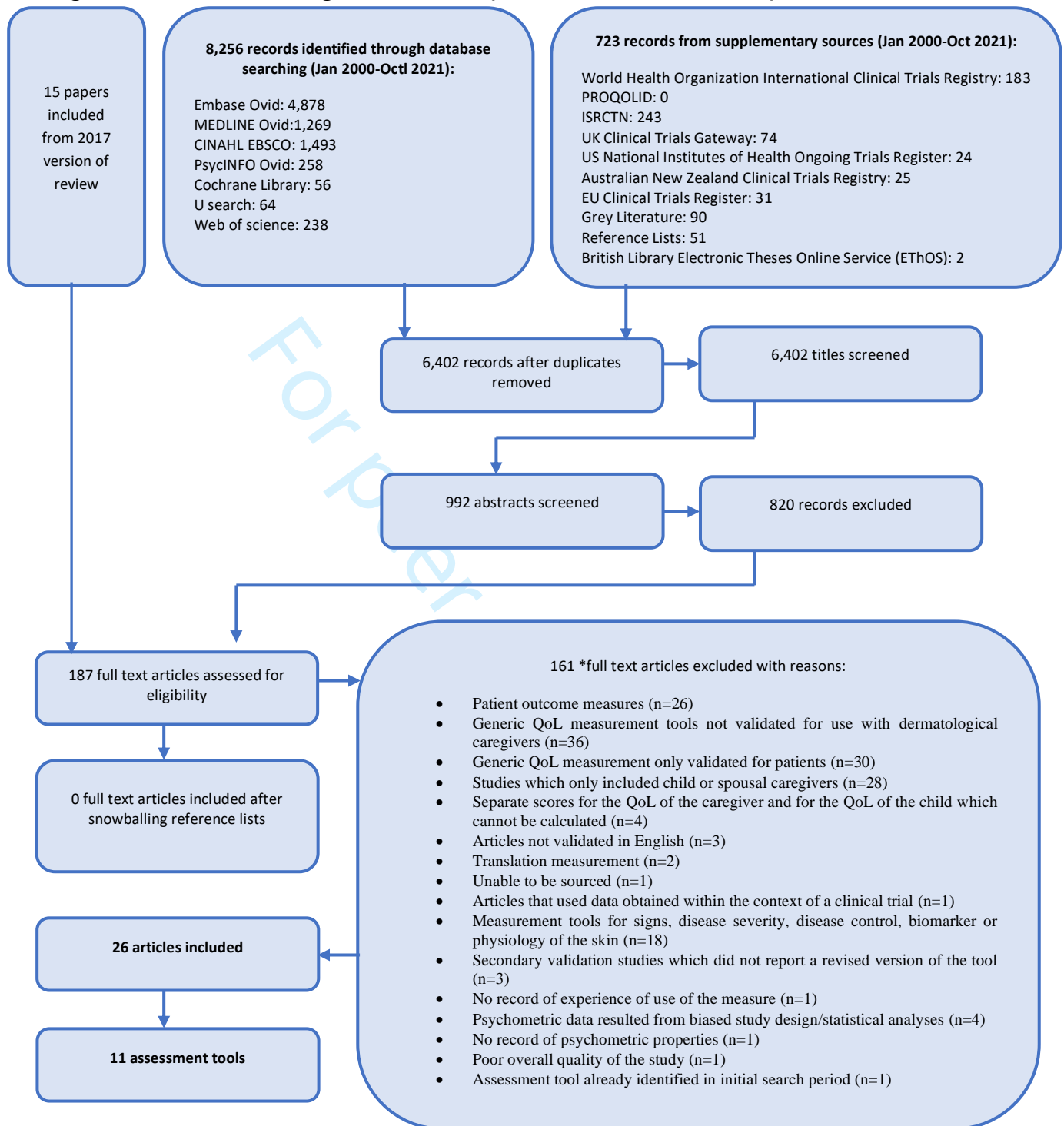
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Figure 1 Legend:

PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.; CINAHL, Cumulated Index to Nursing and Allied Health Literature; EBSCO, Elton B. Stephens Company; PsycINFO, Psychological Information Database; U Search, Ulster University Search; PROQOLID, Patient-Reported Outcome and Quality of Life Instruments Database; ISRCTN, International Standard Randomised Controlled Trials Number; UK, United Kingdom; US, United States; EU, European Union; QoL, Quality of Life.

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Figure 1: PRISMA Flow Diagram for search (01 Jan 2000 to 05 Oct 2021)**Figure 1 Legend:**

PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.; CINAHL, Cumulated Index to Nursing and Allied Health Literature; EBSCO, Elton B. Stephens Company; PsycINFO, Psychological Information Database; U Search, Ulster University Search; PROQOLID, Patient-Reported Outcome and Quality of Life Instruments Database; ISRCTN, International Standard Randomised Controlled Trials Number; UK, United Kingdom; US, United States; EU, European Union; QoL, Quality of Life.

Supplementary file 1: Search Strategy development process

One known relevant systematic review (Sampogna *et al* 2017) was used as a starting point to identify records within databases. A draft search strategy was developed by using candidate search terms that were identified in the titles, abstracts and subject indexing of that systematic review.

Table 1: Preliminary keywords/search terms identified:

Psychosocial or psycho-social or psychodermat* or social or cognit* or emotion* or well-being or psychologic* or adjust* disorder or depress* or anxiety or anxious or coping or stress or mental health or guilt or embarrassment
disease specific or dermatolog* specific or disease burden or burden of disease or scale or needs assessment or psychosocial assessment or index or tool or interview or quality of life or validat* or QoL or measure or impact or screen* or wellbeing or well being or questionnaire or health related quality of life or health profile or inventory or intervention or evaluation or schedule or survey or audit or neuropsychological assessment or activities of daily living or dermatolog* specific health instrument or psychosocial impact or psycho social impact
Caregiver* or family or 'family caregiver' or 'family care giver*' or parent or homecare* or home care* or adult or adults* or grownup* or grown up or families or relative or relation* or mother* or father* or family nurs* or primary care provider* or informal caregiver* or carer* or 'greater patient concept' or homecare
Child or children or infant* or toddler* or baby or babies or youngster* or young pers* or preschool* or teenage* or adolescen* or prematur* or pediatri*
Skin* or skin condition* or skin disorder* or scaliness or keratos* or cornificat* or rare skin dermatology* or chronic disease or chronic condition or long-term condition or chronic illness or incurable or disability or life limiting or long term care or life threatening or palliative or assistive technology or continu* of care or chronic car* or Ichthyos* or continuing car* or impact of chronic skin disease
Skindex or measuring the family impact of dermatological conditions or the family impact of skin diseases

Additional search terms were then identified from the results of that strategy, from the reference list of the systematic review, from systematic searching of each relevant electronic database for relevant “MeSH” terms (included in each search strategy below) and from checking using the PubMed PubReMiner word frequency analysis tool. This strategy was tailored to the specifications of each of the databases searched and developed in collaboration with a subject-specific librarian (J.A.) and expert group. We did not include a specific definition of psychosocial because, given a lack of consensus in the literature on the

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2
3 use of this term, we wanted to include a diverse range of tools (cognitive, social and
4 emotional) to answer the research question.
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7 Pre-planned keyword searches were limited to titles and abstracts, with MeSH terms being
8 exploded, where available. Each of the keywords above were individually mapped to
9 appropriate subject headings (MeSH) in each database, where available, to ensure a broad
10 and thorough search. Each concept was taken individually and OR MeSH with the
11 keyword(s). This process was repeated with all five concepts and were AND together at the
12 end. The Cochrane RCT filter (reported in the Cochrane Handbook v5.2) was used in the
13 development of the MEDLINE strategy. Independent peer review, by both first and second
14 author, involved proofreading the overall structure, spelling and syntax. The search strategy
15 was validated in MEDLINE when it successfully identified the one known systematic review
16 and three of five further studies (Finlay, 1997; Ashcroft *et al* 1998; De Korte *et al* 2002;
17 Bennett *et al* 2003; Haywood *et al* 2005; Nemeth, 2006) identified as part of the strategy
18 development process.
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23 As per eligibility criteria, the original search strategy was limited to English language studies
24 and from studies published between 01 January 2000 to 01 April 2020. We searched in
25 MEDLINE, PsycINFO and EMBASE using the OVID interface. CINAHL EBSCO (Cumulative
26 Index to Nursing and Allied Health Literature) was additionally searched.
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29 Updated searches were conducted on the 5th October 2021 for 01 April 2020 to 5th October
30 2021 (using original search strategies). The PRISMA flow diagram accounts for this updated
31 search and has been included with this submission (Figure 1).
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Supplementary file 2: Database search strategies

Search Strategy for Embase

1. (Psychosocial or psycho-social or psychodermat* or social or cognit* or emotion* or well-being or psychologic* or adjust* disorder or depress* or anxiety or anxious or coping or stress or mental health or guilt or embarrassment).m_titl.
2. mental disease/
3. behavior/ or cognitive therapy/ or behavior disorder/
4. social participation/ or social support/ or social alienation/ or "social determinants of health"/ or social support assessment/ or social isolation/ or social psychiatry/ or social aspect/ or social network/ or social psychology/ or social isolation stress test/ or social behavior/ or Social Interaction Anxiety Scale/ or social norm/ or social life/ or social interaction/ or Social Support Index/ or social stigma/ or "social aspects and related phenomena"/ or social phobia/ or social acceptance/
5. cognitive behavioral stress management/ or Social Cognitive Theory/ or cognitive therapy/
6. psychosocial care/ or Psychosocial Adjustment to Illness Scale/ or psychosocial disorder/
7. anxiety/ or anxiety assessment/
8. emotion assessment/ or emotion/
9. wellbeing/ or psychological wellbeing assessment/
10. coping behavior/
11. guilt/
12. emotion/
13. depression/ or depression assessment/
14. psychological adjustment/ or adjustment disorder/ or adjustment/ or Psychosocial Adjustment to Illness Scale/
15. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
16. (disease specific or dermatolog* specific or disease burden or burden of disease or scale or needs assessment or psychosocial assessment or index or tool or interview or quality of life or validat* or QoL or measure or impact or screen* or wellbeing or well being or questionnaire or health related quality of life or health profile or assessment* or inventory or intervention or evaluation or schedule or survey or audit or neuropsychological assessment or activities of daily living or dermatolog* specific health instrument or psychosocial impact or psycho social impact).m_titl.
17. disease burden/
18. exp questionnaire/ or exp "quality of life"/
19. clinical assessment tool/
20. psychological interview/ or interview/
21. exp "quality of life"/
22. health impact assessment/
23. exp needs assessment/
24. health survey/ or health care survey/
25. daily life activity/

26. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
27. clinical assessment tool/
28. 26 or 27
29. (Caregiver* or family or 'family caregiver' or 'family care giver*' or parent or homecare* or home care* or adult or adults* or grownup* or grown up or families or relative or relation* or mother* or father* or family nurs* or primary care provider* or informal caregiver* or carer or 'greater patient concept' or homecare).m_titl
30. caregiver burden/ or exp caregiver/ or caregiver support/ or Caregiver Strain Index/
31. parent/
32. adult/
33. home care/
34. family functioning/ or family coping/ or family life/ or family centered care/ or family stress/ or family health/ or exp family assessment/or exp family/
35. relative/
36. sibling/
37. grandparent/
38. 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37
39. (Ichthyos* or Skin* or skin condition* or skin disorder* or scaliness or keratos* or cornificat* or rare skin dermatology* or chronicdisease or chronic condition or long term condition or chronic illness or incurable or disability or life limiting or long term care or life threatning or palliative or assistive technology or continu* of care or chronic car* or continuing car* or impact of chronic skin diseese).m_titl.
40. "ichthyosis bullosa of Siemens"/ or X linked ichthyosis/ or ichthyosis/ or lamellar ichthyosis/ or ichthyosis vulgaris/
41. exp skin/ or exp skin disease/
42. psychological rating scale/ or Psychosocial Adjustment to Illness Scale/
43. chronic disease/
44. rare disease/
45. diseases/co, dm [Complication, Disease Management]
46. palliative nursing/
47. eczema/
48. "Psoriasis Area and Severity Index"/ or psoriasis vulgaris/ or Psoriasis Severity Index/ or scalp psoriasis/ or exp psoriasis/
49. atopic dermatitis/ or exp dermatitis/
50. 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49
51. (Child or children or infant* or toddler* or baby or babies or youngster* or young pers* or preschool* or teenage* or adolescen* orprematu*).m_titl.

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Search Strategy for MEDLINE

1	mental disorders/ or anxiety disorders/ or dissociative disorders/ or mood disorders/ or
2	neurocognitive disorders/ or neurotic disorders/ or personality disorders/ or sexual
3	dysfunctions, psychological/ or sleep wake disorders/ or substance-related disorders/ or
4	"trauma and stressor related disorders"/
5	
6	2
7	Psychiatry/nu, is [Nursing, Instrumentation]
8	
9	3
10	exp fatigue/ or exp behavioral symptoms/
11	
12	4
13	Stress, Psychological/co, di, ge, mo, nu, px [Complications, Diagnosis, Genetics,
14	Mortality, Nursing, Psychology]
15	
16	5
17	Depressive Disorder/nu, px [Nursing, Psychology]
18	
19	6
20	Anxiety/ or Anxiety, Separation/ or Anxiety Disorders/ or Performance Anxiety/
21	
22	7
23	Personal Satisfaction/
24	
25	8
26	Social Stigma/ or Social Support/ or Social Behavior/ or Social Isolation/ or "Social
27	Determinants of Health"/ or Social Perception/ or Psychology, Social/ or Social
28	Marginalization/
29	
30	9
31	Depression/nu, px [Nursing, Psychology]
32	
33	10
34	Anxiety/ or Stress, Psychological/ or Adaptation, Psychological/ or Depression/
35	
36	11
37	Stress, Psychological/nu, px [Nursing, Psychology]
38	
39	12
40	Guilt/px [Psychology]
41	
42	13
43	Embarrassment/ or Emotions/
44	
45	14
46	Behavior, Animal/is [Instrumentation]
47	
48	15
49	Cognition Disorders/ or Cognition/
50	
51	16
52	Social Stigma/ or Social Values/ or Social Participation/ or Social Behavior Disorders/ or
53	Social Support/ or Social Behavior/ or Social Isolation/ or Social Perception/ or
54	Psychology, Social/ or Phobia, Social/ or Social Skills/ or Social Networking/ or Social
55	Marginalization/
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57	17
58	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
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	limit 17 to abstracts
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	(Psychosocial or psycho-social or psychodermat* or social or cognit* or emotion* or
	well-being or psychologic* or adjust* disorder or depress* or anxiety or anxious or
	coping or stress or mental health or guilt or embarrassment).m_titl.
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	limit 19 to abstracts

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4	21	18 or 20
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6	22	(disease specific or dermatolog* specific or disease burden or burden of disease or
7		scale or validat* or needs assessment or psychosocial assessment or index or tool or
8		interview or quality of life or QoL or measure or impact or screen* or wellbeing or well
9		being or questionnaire or health related quality of life or health profile or inventory or
10		intervention or evaluation or schedule or survey or audit or neuropsychological
11		assessment or activities of daily living or dermatolog* specific health instrument or
12		psychosocial impact or psycho social impact).m_titl.
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15		
16	23	limit 22 to abstracts
17		
18	24	"Quality of Life"/px [Psychology]
19		
20	25	"Surveys and Questionnaires"/
21		
22	26	"Health Services Needs and Demand"/ or Needs Assessment/
23		
24	27	"Outcome Assessment (Health Care)"/ or Personality Assessment/ or Self-Assessment/
25		or Nursing Assessment/ or "Process Assessment (Health Care)"/ or Symptom
26		Assessment/ or "Outcome and Process Assessment (Health Care)"/
27		
28		
29	28	"Severity of Illness Index"/
30		
31	29	"Tool Use Behavior"/
32		
33	30	"Quality of Life"/px [Psychology]
34		
35	31	Interview, Psychological/ or Interview/
36		
37	32	"Activities of Daily Living"/px [Psychology]
38		
39	33	23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32
40		
41	34	limit 33 to abstracts
42		
43	35	23 or 34
44		
45	36	(Caregiver* or family or 'family caregiver' or 'family care giver*'or parent or homecare*
46		or home care* or adult or adults* or grownup* or grown up or families or relative or
47		relation* or mother* or father* or family nurs* or primary care provider* or informal
48		caregiver* or carer* or 'greater patient concept' or homecare).m_titl.
49		
50	37	limit 36 to abstracts
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52	38	Caregivers/px [Psychology]
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54	39	Family/ or Family Health/ or Family Nursing/
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56	40	Parents/px [Psychology]
57		
58	41	Adult/px [Psychology]
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60	42	Humans/px [Psychology]

43	Siblings/px [Psychology]
44	Grandparents/px [Psychology]
45	38 or 39 or 40 or 41 or 42 or 43 or 44
46	limit 45 to abstracts
47	37 or 46
48	(Ichthyos* or Skin* or skin condition* or skin disorder* or scaliness or keratos* or cornificat* or rare skin dermatology* or chronic disease or chronic condition or long term condition or chronic illness or incurable or disability or life limiting or long term care or life threatening or palliative or assistive technology or continu* of care or chronic car* or continuing car* or impact of chronic skin disease).m_titl.
49	limit 48 to abstracts
50	Ichthyosis/ or Ichthyosis Vulgaris/ or Ichthyosis, X-Linked/ or Ichthyosis, Lamellar/ or "Ichthyosis Bullosa of Siemens"/
51	exp Skin/ or exp Skin Diseases/
52	exp Dermatology/
53	Psoriasis/ or Scalp Dermatoses/
54	exp Dermatitis/ or exp Dermatitis, Atopic/
55	Eczema/
56	Chronic Disease/
57	Rare Diseases/
58	Palliative Care/ or Terminal Care/ or Chronic Disease/
59	50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58
60	limit 59 to abstracts
61	49 or 60
62	21 and 35 and 47 and 61
63	limit 62 to (english language and yr="2000 -Current")
64	exp Child/
65	exp Infant/
66	Child, Preschool/ or Infant/
67	Adolescent/ or Young Adult/
68	Infant, Premature, Diseases/ or Infant, Premature/ or Infant, Extremely Premature/ or Premature Birth/

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71	(Child or children or infant* or toddler* or baby or babies or youngster* or young pers* or preschool* or teenage* or adolescen* or prematur*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
72	limit 71 to abstracts
73	21 and 35 and 47 and 61 and 72
74	21 and 35 and 47 and 61
75	limit 74 to (english language and yr="2000 -Current")

Search Strategy for PsychINFO

1		(Psychosocial or psycho-social or psychodermat* or
2		social or cognit* or emotion* or well-being or
3		psychologic* or adjust* disorder or depress* or anxiety or
4		anxious or coping or stress or mental health or guilt or
5		embarrassment).m_titl.
6	<input type="checkbox"/>	2
7		limit 1 to abstracts
8	<input type="checkbox"/>	3
9		Psychosocial Factors/ or Major Depression/
10	<input type="checkbox"/>	4
11		exp Psychosocial Assessment/
12	<input type="checkbox"/>	5
13		Mental Health/ or Well Being/ or Life Satisfaction/ or
14		Anxiety/
15	<input type="checkbox"/>	6
16		Psychological Stress/ or Stress/ or Chronic Stress/ or
17		Social Stress/
18	<input type="checkbox"/>	7
19		Guilt/
20	<input type="checkbox"/>	8
21		exp Embarrassment/
22	<input type="checkbox"/>	9
23		Social Identity/ or Social Isolation/ or Social Anxiety/ or
24		Social Cognition/
25	<input type="checkbox"/>	10
26		3 or 4 or 5 or 6 or 7 or 8 or 9
27	<input type="checkbox"/>	11
28		limit 10 to abstracts
29	<input type="checkbox"/>	12
30		2 or 11
31	<input type="checkbox"/>	13
32		(disease specific or dermatolog* specific or disease
33		burden or burden of disease or scale or needs
34		assessment or psychosocial assessment or index or tool
35		or interview or quality of life or validat* or QoL or measure
36		or impact or screen* or wellbeing or well being or
37		questionnaire or health related quality of life or health
38		profile or inventory or intervention or evaluation or
39		schedule or survey or audit or neuropsychological
40		assessment or activities of daily living or dermatolog*
41		specific health instrument or psychosocial impact or
42		psycho social impact).m_titl.
43	<input type="checkbox"/>	14
44		limit 13 to abstracts

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<input type="checkbox"/>	15	Test Reliability/ or Test Validity/ or "Quality of Life"/ or Measurement/ or Psychometrics/ or Questionnaires/
<input type="checkbox"/>	16	exp Caregiver Burden/
<input type="checkbox"/>	17	Questionnaires/
<input type="checkbox"/>	18	exp Rating Scales/ or exp Screening Tests/
<input type="checkbox"/>	19	Rating Scales/ or Screening Tests/
<input type="checkbox"/>	20	exp Needs Assessment/
<input type="checkbox"/>	21	measurement/ or needs assessment/ or "quality of life measures"/ or interviews/
<input type="checkbox"/>	22	"Activities of Daily Living"/
<input type="checkbox"/>	23	Surveys/
<input type="checkbox"/>	24	15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
<input type="checkbox"/>	25	limit 24 to abstracts
<input type="checkbox"/>	26	14 and 25
<input type="checkbox"/>	27	(Caregiver* or family or 'family caregiver' or 'family care giver*'or parent or homecare* or home care* or adult or adults* or grownup* or grown up or families or relative or relation* or mother* or father* or family nurs* or primary care provider* or informal caregiver* or carer* or 'greater patient concept' or homecare).m_titl.
<input type="checkbox"/>	28	exp Caregivers/
<input type="checkbox"/>	29	Family/ or Extended Family/ or Family Members/
<input type="checkbox"/>	30	Home Care/ or Home Care Personnel/
<input type="checkbox"/>	31	limit 27 to abstracts
<input type="checkbox"/>	32	28 or 29 or 30
<input type="checkbox"/>	33	limit 32 to abstracts
<input type="checkbox"/>	34	31 or 33
<input type="checkbox"/>	35	(Ichthyos* or Skin* or skin condition* or skin disorder* or scaliness or keratos* or cornificat* or rare skin dermatology* or chronic disease or chronic condition or long term condition or chronic illness or incurable or disability or life limiting or long term care or life threatening or palliative or assistive technology or

		continu* of care or chronic car* or continuing car* or impact of chronic skin disease).m_titl.
<input type="checkbox"/>	36	limit 35 to abstracts
<input type="checkbox"/>	37	exp Skin Disorders/
<input type="checkbox"/>	38	Dermatitis/
<input type="checkbox"/>	39	Chronic Illness/ or Genetic Disorders/
<input type="checkbox"/>	40	Long Term Care/
<input type="checkbox"/>	41	Palliative Care/
<input type="checkbox"/>	42	37 or 38 or 39 or 40 or 41
<input type="checkbox"/>	43	36 or 42
<input type="checkbox"/>	44	12 and 26 and 34 and 43
<input type="checkbox"/>	45	limit 44 to (english language and yr="2000 -Current")

Search Strategy for CINAHL

#	Query	Limiters/Expanders
		Limiters - Published Date: 20000101-2021105; English Language Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S58	S14 AND S33 AND S44 AND S57	
S57	S52 OR S53 OR S54 OR S55 OR S56	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S56	(MH "Dermatology")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S55	(MH "Keratosis+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S54	(MH "Skin+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S53	(MH "Ichthyosis+") OR (MH "Ichthyosiform Erythroderma, Congenital+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S52	ichthyo* or skin* or scaliness or kerato* or cornificat* or dermatolog*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S51	S45 OR S46 OR S47 OR S48 OR S49 OR S50	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S50	(MH "Infant, Premature")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S49	(MH "Adolescence+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S48	(MH "Child, Preschool")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S47	(MH "Infant+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S46	(MH "Child+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S45	child* or infant* or toddler* or baby or babies or youngster* or "young pers*" or preschool* or teen* or adolescen* or prematur* or pediatric* or paediatric*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S44	S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S43	(MH "Primary Health Care")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S42	(MH "Family Nursing")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S41	(MH "Fathers+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S40	(MH "Mothers+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S39	(MH "Adult+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S38	(MH "Home Health Care+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S37	(MH "Parents+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S36	(MH "Family+") OR (MH "Extended Family+") OR (MH "Nuclear Family+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S35	(MH "Caregivers")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S34	caregiver* or family or "family caregiver" or "family care giver*" or parent or homecare* or "home care*" or adult or adults* or grownup* or "grown up" or families or relative* or relation* or mother* or father* or "family nurs*" or "primary care provider*" or "informal caregiver*" or carer* or "greater patient concept" or homecare	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S33	S15 OR S32	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S32	S31 N5 S30	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S31	("disease specific" or "dermatolog* specific" or "disease burden" or "burden of disease")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S30	S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S29	(MH "Activities of Daily Living+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S28	(MH "Audit")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S27	(MH "Surveys+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S26	(MH "Evaluation+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S25	(MH "Psychosocial Intervention")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S24	(MH "Inventories")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S23	(MH "Questionnaires+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S22	(MH "Psychological Well-Being")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S21	(MH "Health Screening+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S20	(MH "Interviews+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S19	(MH "Clinical Assessment Tools+") OR (MH "Research Instruments+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S18	(MH "Scales")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S17	(MH "Needs Assessment")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S16	(MH "Quality of Life+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S15	(“disease specific” or “dermatolog* specific” or “disease burden” or “burden of disease”) N5 (scale or “needs assessment” or “psychosocial assessment” or index or tool or interview or “quality of life” or validat* or QoL or measure or impact or screen* or wellbeing or “well being” or well-being or questionnaire or “health profile” or inventory or intervention or evaluation or schedule or survey or audit or “neuropsychological assessment” or “activit* of daily living” or “health instrument” or “psychosocial impact” or “psycho social impact”)	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S14	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S13	(MH "Embarrassment")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S12	(MH "Guilt+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S11	(MH "Mental Health")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S10	(MH "Coping+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S9	(MH "Anxiety+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S8	(MH "Depression+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S7	(MH "Adjustment Disorders+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S6	(MH "Adjustment Disorders+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S5	(MH "Stress, Psychological+") OR (MH "Diagnosis, Psychosocial+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S4	(MH "Psychological Well-Being")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S3	(MH "Emotions+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S2	(MH "Social Cognition") OR (MH "Cognition+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase
S1	psychosocial or psycho-social or psychodermat* or social or cognit* or emotion* or well-being or wellbeing or "well being" or psychologic* or "adjust* disorder" or depress* or anxiety or anxious or coping or stress or "mental health" or guilt or embarrassment	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

Search Strategy for Cochrane Central Register of Controlled Trials (CENTRAL)

'Skin' AND 'caregiver' AND 'skin disease' AND 'dermatological tool' were searched using the advanced search function.

Search Strategy for U Search

'Caregiver' AND 'dermatology or skin disease' AND 'measurement tool or assessment tool' AND 'children or adolescents or youth or child or teenager' were searched using the advanced search function.

Search Strategy for Web of Science

Query preview was '[ALL=(dermatology assessment tools)) AND ALL=(caregivers)]

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Supplementary file 3: Number of records identified during supplementary searches

Grey literature, bibliographies, online databases of QoL tools and several trial registers were searched on 01 April 2020 and updated on 05 Oct 2021.

Table 1: Records identified during original and updated supplementary searches

Tools included in search	Search category/term	Records (n) identified during original search (01 Jan 2000 to 01 April 2020)	Records (n) identified during updated search (01 April 2020 to 05 Oct 2021)	Number accessed in full text	Relevant (included in review)
Controlled Trials ISRCTN (www.controlled-trials.com/isrctn/)	'Skin and Connective Tissue Diseases'	241	2	3	0
United Kingdom (UK) Clinical Trials Gateway (www.ukctg.nihr.ac.uk/default.aspx)	'Skin and Cosmetic health'	72	2	0	0
United States(US) National Institutes of Health Ongoing Trials Register (www.clinicaltrials.gov)	'caregiver' and 'skin diseases'	24	0	1	0 (recruitment stage)
Australian New Zealand Clinical Trials Registry (www.anzctr.org.au)	'caregiver' and 'skin'	25	0	0	0
World Health Organization International Clinical Trials Registry platform (www.who.int/trialsearch)	'skin' and 'caregiver'	182	1	0	0
EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/)	'skin' and 'caregiver'	30	1	0	0
British Library Electronic Theses Online Service (EThOS) was searched using several combinations of key words	skin, instrument, caregiver, validation, psychosocial	0	2	2	0
OpenGrey database (www.opengrey.eu/) was searched (up to 22 November 2013)	'Skin Diseases'	89	1	0	0
Patient-Reported Outcome and Quality of Life Instruments Database (PROQOLID) (2002)		0	0	0	0
Handsearching of the bibliographies of included and excluded studies		48	3	0	0
Total		711	12	6	0

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For peer review only

Supplementary file 4: Methodological domains of the risk of bias criteria

Domains	Definitions	Grades and Criteria		
Validity Conceptual ¹ Construct ² Convergent ³	Does the tool measure what it is supposed to measure? Are the relevant domains captured? Does tool confirm hypothesized difference (eg diagnosis, clinical disease severity, others) Does the tool relate to other tools measuring the same construct?	A1: well balanced, objective and subjective domains B1: more focused on objective or subjective domains C1: missing important HRQOL domains	A2: >75% of results are in accordance with specific hypotheses B2: <75 of results are in accordance with specific hypotheses C2: no information	A3: correlation > B3: correlation < C3: no information
Interpretability Norms Categorization MCID ⁴	Are there standard comparative data from the general population and/or dermatology patients published and/or available? Are there categories of the obtained score available? Has the minimal change that is relevant to patients been reported?	A1: general and dermatology patients B1: general or dermatology patients C1: general nor dermatology patients	A2: using anchor or banding techniques B2: using distribution-based techniques C2: not reported	A3: MCID is known in heterogeneous sample B3: MCID is known in limited sample C3: not reported
Reliability ^{3,6} Internal consistency Retest-reliability	Does the tool provide a consistent answer? The extents to which items in a (sub) scale are intercorrelated, thus measuring the same construct (Cronbach's x)? Does a repeated administration of the tool within a reasonable period result in a similar outcome?	A1: 0.95 > Cronbach's x > 0.70 B1: Cronbach's x < 0.7 or > 0.95 C: Cronbach's x not reported	A2: x or ICC > 0.7 B2: x or ICC < 0.7 or correlation coefficients > 0.7 C2: x or ICC not reported or correlation coefficient < 0.7	
Structure	Have the domains and/or summary score of the tool been confirmed?	A: item response theory B: Factor analysis C: no factor analysis or item response theory		
Responsiveness	Is the tool sensitive to detect changes over time or due to therapy using patient centred and/or clinical criteria?	A: strong B: moderate or conflicting evidence C: absent, weak or solely based on statistical evidence		

Domains	Definitions	Grades and Criteria	
Item bias	Do the items of the tool function similar across external factors such as age, gender and diagnosis?	A: strong B: moderate or conflicting evidence C: absent or weak	
Cultural issues	Has the tool been translated using guidelines?	A1: always	A2: always
Translations	Has the tool been analysed in a cultural	B1: sometimes	B2: sometimes
Cultural equivalence	equivalence study?	C1: never, not reported	C2: never
Respondent burden	Is the length and content acceptable to the patients?	A: brief (<15min) B: long or problems of acceptability C: long and problems of acceptability	
Administrative burden	How easy is the tool to administer, score and interpret?	A: simple B: moderate C: complex	
Alternative forms	Is the tool available and tested for alternate forms of administration such as interviews in person or telephone, self-administration or computer-assisted interviews	A: strong evidence B: moderate or conflicting evidence C: absent or weak evidence	
Legend: ICC, intraclass correlation coefficient; ¹ Adjusted from Lohr et al (1996); Andresen (2000) and Terwee et al (2007); ² Objective and subjective domains are described by Muldoon et al (1998); ³ Criteria of construct validity and reliability were based on description by Terwee et al (2007); ⁴ MCID, minimal clinically important difference (ie the minimal difference, which is measured and is relevant to a patient and is not due to intrinsic variance of the instrument); ⁵ Refer to Table 2; ⁶ Reliability is concerned with the temporal stability of instrument scores (test-retest) and internal consistency, which is estimated by Cronbach's x, evaluates the relationship between all items (of a scale) and their ability to measure a single underlying domain. Test-retest reliability assess score consistency over two points in time assuming no change in health status and may provide a more rigorous of reliability due to the different sources of variance. Test-retest reliability should best be expressed in a x coefficient or ICC. Spearman's correlation coefficients are less optimal for retest reliability.			

Supplementary file 5: Figure 1:PRISMA Flow Chart for initial search (Jan 2000-April 2020)

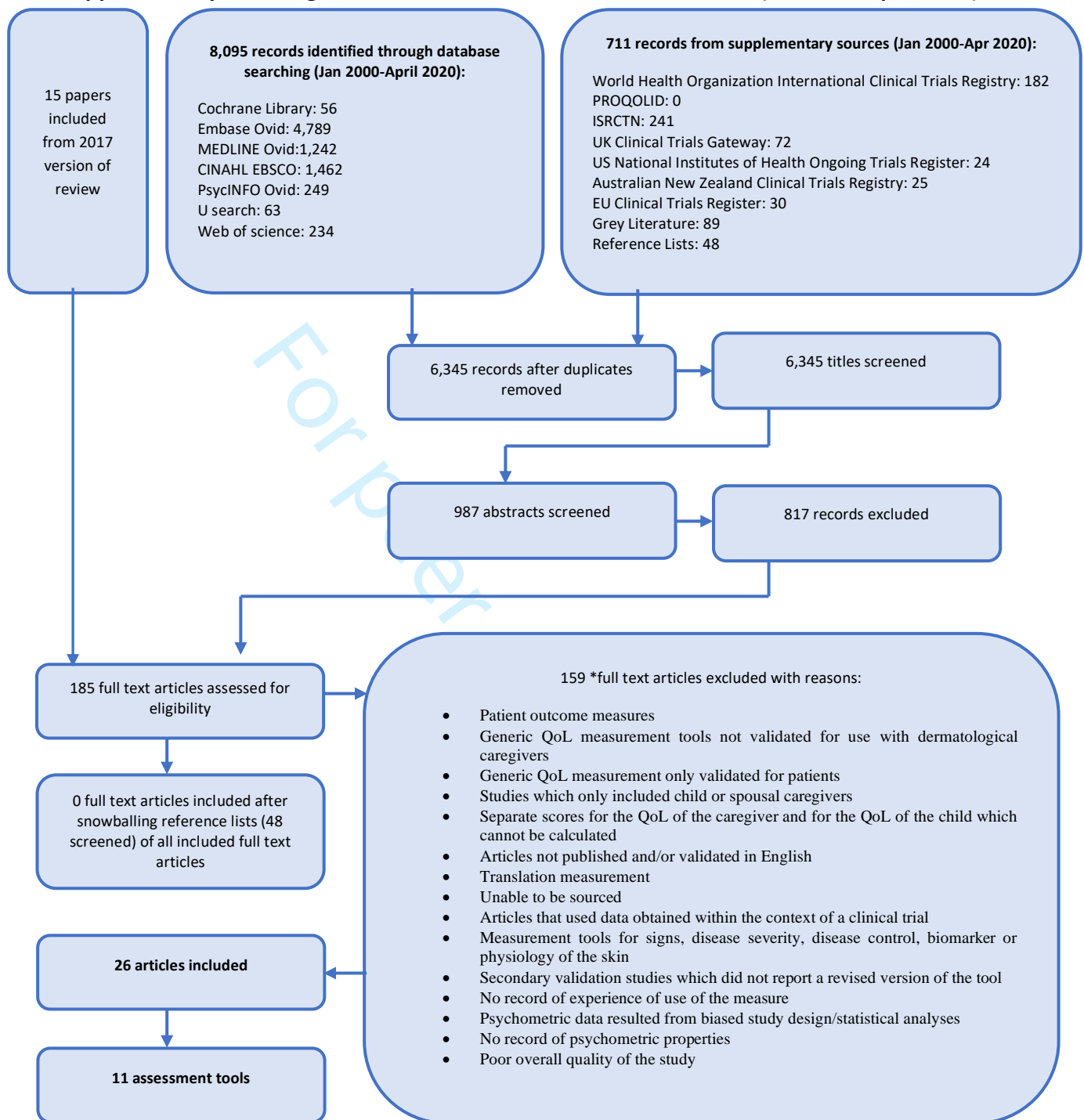


Figure 1 Legend:

PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.; CINAHL, Cumulated Index to Nursing and Allied Health Literature; EBSCO, Elton B. Stephens Company; PsycINFO, Psychological Information Database; U Search, Ulster University Search; PROQOLID, Patient-Reported Outcome and Quality of Life Instruments Database; ISRCTN, International Standard Randomised Controlled Trials Number; UK, United Kingdom; US, United States; EU, European Union; QoL, Quality of Life.

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New studies included from updated search

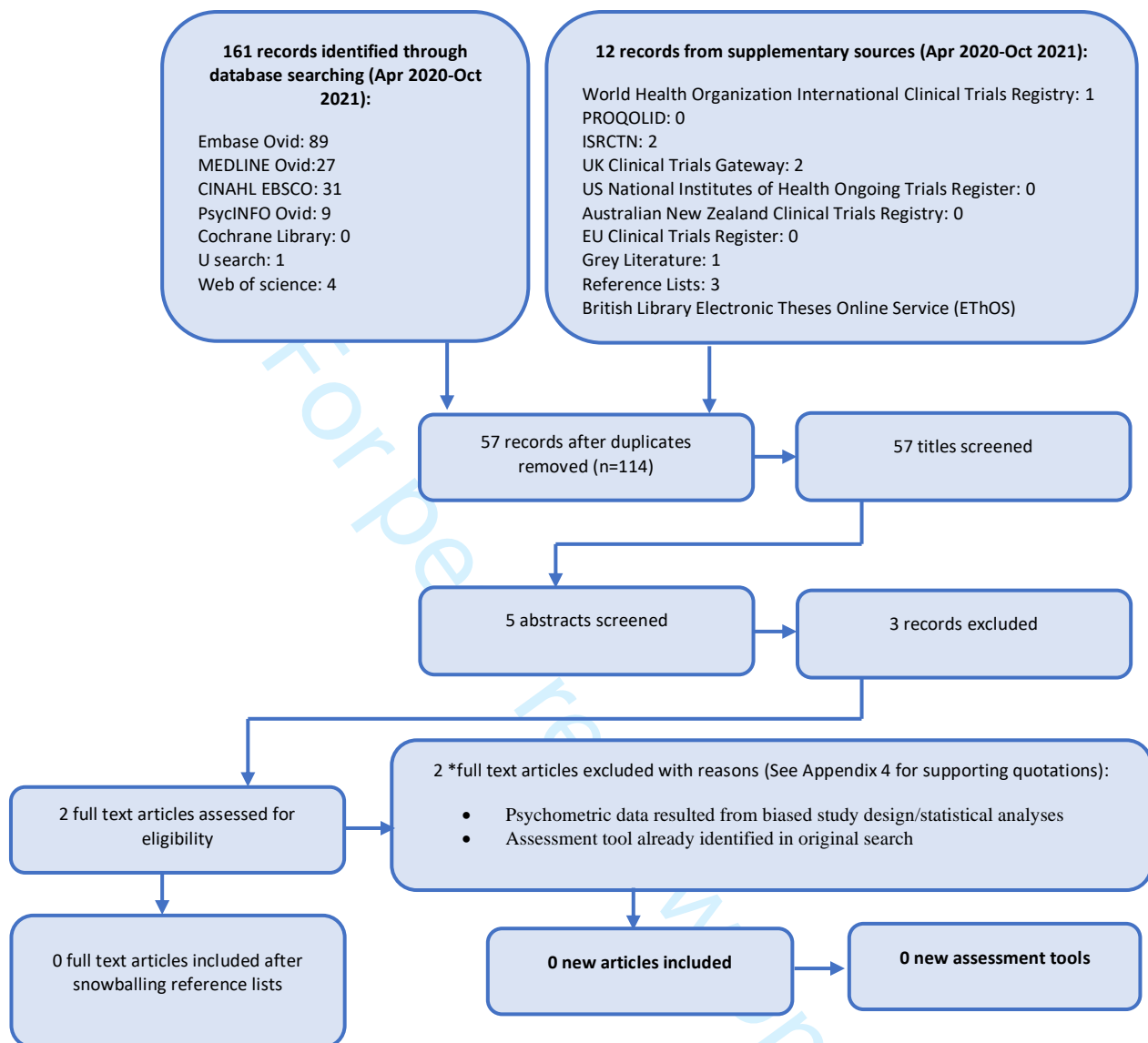
During the updated search, a total of 173 records were identified. 161 records were identified from database searches and an additional 12 records were identified from supplementary searches. In total, 57 records were available after duplicates (n=114) were removed. 57 titles were screened. 5 abstracts were screened and 2 full text record were assessed for eligibility.^{1,2}

One record¹ identified no new measurement tool, with the **Family Dermatology Life Quality Index (FDLQI)** already included in our initial search. The second record² was excluded for a reason as listed in the exclusion criteria in Figure 1 (psychometric data resulted from biased study design). This exclusion was also justified by quotations from the paper (‘Validity was established in a limited range of subjects’, ‘the parents that responded to the survey were all mothers’, ‘The present study was a single-institution cross-sectional study in Japan targeting parents of infants and toddlers (first-time patients less than 7 years old)’).

In summary, no new studies and no new assessment tools were identified in our updated review. Please see PRISMA flow diagram (fig.2) below.

References

1. Zychowska M, Reich A, Maj J, Jankowska-Konsur A, Szepietowski J. Impact of Childhood Psoriasis on Caregivers’ Quality of Life, Measured with Family Dermatology Life Quality Index. *J Eur Acad Dermatol Venereol* 2020; 100.
2. Sato H, Goto A, Murakami M, Kawabata Y. Development of a Pediatric Dermatology Screening tool based on Two Parent-Reported Skin Symptoms: Comparison of Parental Recognition and Physician Diagnosis of Skin Symptoms of Infants and Toddlers. *J Prim Care Community Health* 2020;11: 1-7.

Figure 2: PRISMA Flow Diagram for updated search (01 Apr 2020 to 05 Oct 2021)**Figure 2 Legend:**

PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.; CINAHL, Cumulated Index to Nursing and Allied Health Literature; EBSCO, Elton B. Stephens Company; PsycINFO, Psychological Information Database; U Search, Ulster University Search; PROQOLID, Patient-Reported Outcome and Quality of Life Instruments Database; ISRCTN, International Standard Randomised Controlled Trials Number; UK, United Kingdom; US, United States; EU, European Union.



PRISMA 2020 Checklist

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Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Pg. 1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Pg. 2,3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Pg. 5
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Pg. 5
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Pg. 6,7, PROSPERO database, Figure 1
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Pg.6, Supplementary Information Files 2 and 3
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Supplementary Information Files 2 and 3
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Pg. 6,7
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Pg.6, 7, 8
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Pg.7, 8
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Pg.3, 7, 8
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Pg.7, Supplementary Information File 4, Table 4
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Pg.7, Tables 1,2,3
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Pg.7, Tables 1,2,3
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Pg.7
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Pg.7, 8



PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Pg. 7, Supplementary Information File 4
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Supplementary Information File 4, Table 4
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Pg.8, Supplementary Information File 1, Table 3, Table 4
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Supplementary Information File 1, Table 4
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Pg. 8, Supplementary Information File 1
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Pg. 8-13, Figure 1, Tables 1-4, Supplementary Information File 5.
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Pg. 9, Supplementary information File 5
Study characteristics	17	Cite each included study and present its characteristics.	Pg. 9-13, Tables 1-4
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Table 4, Supplementary Information File 4
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Pg. 12,13, Table 3
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Pg. 9-13, Table 4, Supplementary Information



PRISMA 2020 Checklist

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Section and Topic	Item #	Checklist item	Location where item is reported
			File 4
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Pg. 12, 13
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Pg. 12,13, Table 4, supplementary Information File 4
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Pg. 12,13, Tables 3, 4
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Table 4
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Pg. 7, Supplementary Information file 1, Table 4
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Pg. 22-24
	23b	Discuss any limitations of the evidence included in the review.	Pg. 22-24
	23c	Discuss any limitations of the review processes used.	Pg. 4, 24
	23d	Discuss implications of the results for practice, policy, and future research.	Pg. 23-25
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Pg. 3
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Pg. 3
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Pg. 26
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Pg. 3
Competing interests	26	Declare any competing interests of review authors.	Pg. 26
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Supplementary Information Files 1-5, Tables 1-4, Figure 1.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

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